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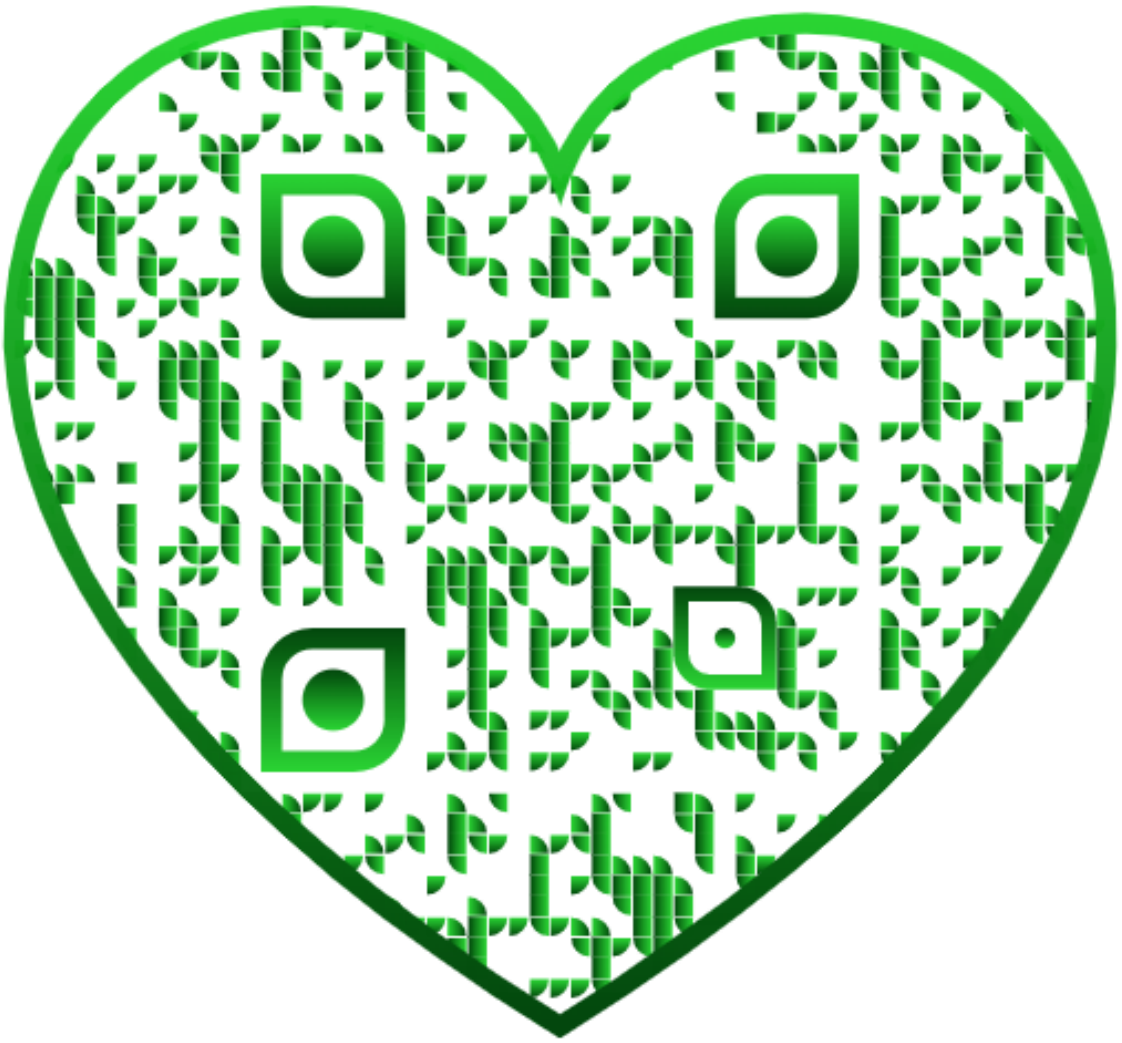

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Chapter 1: Introduction

Chapter description

This introductory chapter addresses overview of national drug policy development and its implementation, essential medicines concept, formulary process and Pharmaceutical Sector Transformation Plan of Ethiopia.

Learning Objectives

At the end of this chapter, students will be able to:

- ✓ Describe national drug policy
- ✓ Identify the core objectives and key strategies of NDP
- ✓ Explain the development and implementation of NDP
- ✓ Explain concept of essential medicine
- ✓ Describe formulary process
- ✓ Discuss Pharmaceutical Sector Transformation Plan of Ethiopia

1.1 National Drug Policy

1.1.1 Definition and scope of national drug policy

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field. A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

1.1.2 Why is a national drug policy needed?

A national drug policy is needed for many reasons. The most important are:

- ✓ to present a formal record of values, aims, decisions and medium- to long-term government commitments;
- ✓ to define the national goals and objectives for the pharmaceutical sector, and set priorities;
- ✓ to identify the strategies needed to meet those objectives, and identify the various factors responsible for implementing the main components of the policy;
- ✓ to create a forum for national discussions on these issues

The consultations and national discussions preceding the drug policy document are very important, as they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This is crucial in view of the national effort that will later be necessary to implement the policy. The policy process is just as important as the policy document. The guidelines set out here are intended to help countries develop and implement a comprehensive policy framework that is appropriate to their own needs, priorities and resources.

A national drug policy is an essential part of health policy. A national drug policy cannot be developed in a vacuum. It must fit within the framework of a particular health care system, a national health policy and, perhaps, a program of health sector reform. The goals of the national

drug policy should always be consistent with broader health objectives, and policy implementation should help to achieve those broader objectives. The health policy and the level of service provision in a particular country are important determinants of drug policy and define the range of choices and options. On the other hand, the drug situation also affects the way in which health services are regarded in that health services lose their credibility if there is no adequate supply of good quality drugs, or if these are badly prescribed. Thus the implementation of an effective drug policy promotes confidence in and use of health services. There are also economic arguments. In many countries a large proportion of health care spending is on drugs. Health care financing is therefore closely related to drug financing. It is very difficult to implement a health policy without a drug policy.

Learning Activity 1.1

a. Why do we need a National Drug Policy?

1.2 Objectives and key strategies of a national drug policy

1.2.1 Objectives of a national drug policy

In the broadest sense a national drug policy should promote equity and sustainability of the pharmaceutical sector. The goals of NDP:

A. Health related goal

- ✓ Ensure essential drugs are available and affordable
- ✓ Ensure quality, safety and efficacy of drugs
- ✓ Improve prescribing and dispensing practices
- ✓ Promote the correct use of medication

B. Economic goal

- ✓ To reduce foreign exchange expenditures for pharmaceuticals without reducing the supply
- ✓ Lower the cost of medicines to the government, other health care providers, and the public

- ✓ To provide jobs in pharmaceutical supply and possibly production
- ✓ Attain sustainable financing

C. National development goal

- ✓ To improve internal communication systems
- ✓ Increase skills of personnel in management, pharmacy, and medicine.
- ✓ Create reliable supply systems that incorporate a mix of public and private supply services
- ✓ To facilitate national pharmaceutical production

The general health related objectives of a national drug policy are to ensure:

Access: equitable availability and affordability of essential drugs

Quality: - the quality, safety and efficacy of all medicines

Rational use: - the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers.

The more specific goals and objectives of NDP will depend up on:

- ✓ The structure of the health care system
- ✓ The number of trained pharmacists and physicians
- ✓ The capacity of the drug regulatory authority
- ✓ The way in which pharmaceuticals are distributed or
- ✓ The level of funding available for pharmaceuticals
- ✓ political priorities set by the government

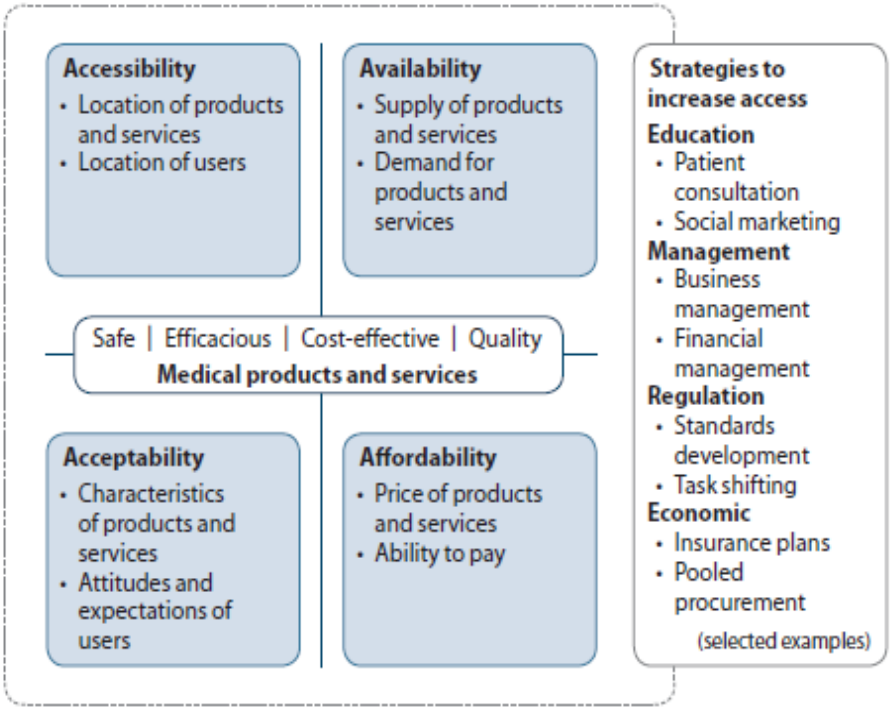
It is critical that all the drug policy‘s objectives are explicit, so that the roles of the public and private sectors and of the various ministries (health, finance, trade and industry) and government bodies (such as the drug regulatory authority) can be specified.

Four dimensions of access have particular relevance to essential medicines, vaccines, and other health commodities:-

- ✓ **Availability**, defined by the relationship between the type and quantity of product or service needed, and the type and quantity of product or service provided.
- ✓ **Affordability**, defined by the relationship between prices of the products or services and the user’s ability to pay for them

- ✓ **Accessibility**, defined by the relationship between the location of the product or service and the location of the eventual user of the product or service
- ✓ **Acceptability** (or satisfaction), defined by the relationship between the user's attitudes and expectations about the products and services and the actual characteristics of products and services

Increasing access framework



Source: CPM/MSH 2011.

The national drug policy and its implementation plan focused on two strategies to improve **access** to essential medicines;

- Appropriate selection and use of generic drugs, and
- Improved drug procurement and management (through movement channel and in the health facility)

Improving access to essential medicines is perhaps the most complex challenge for all health sectors involved in the field of medicines supply. However, it is possible to improve the

accessibility of essential medicine through the four components of the “access framework” is essential but not sufficient in itself to ensure access.

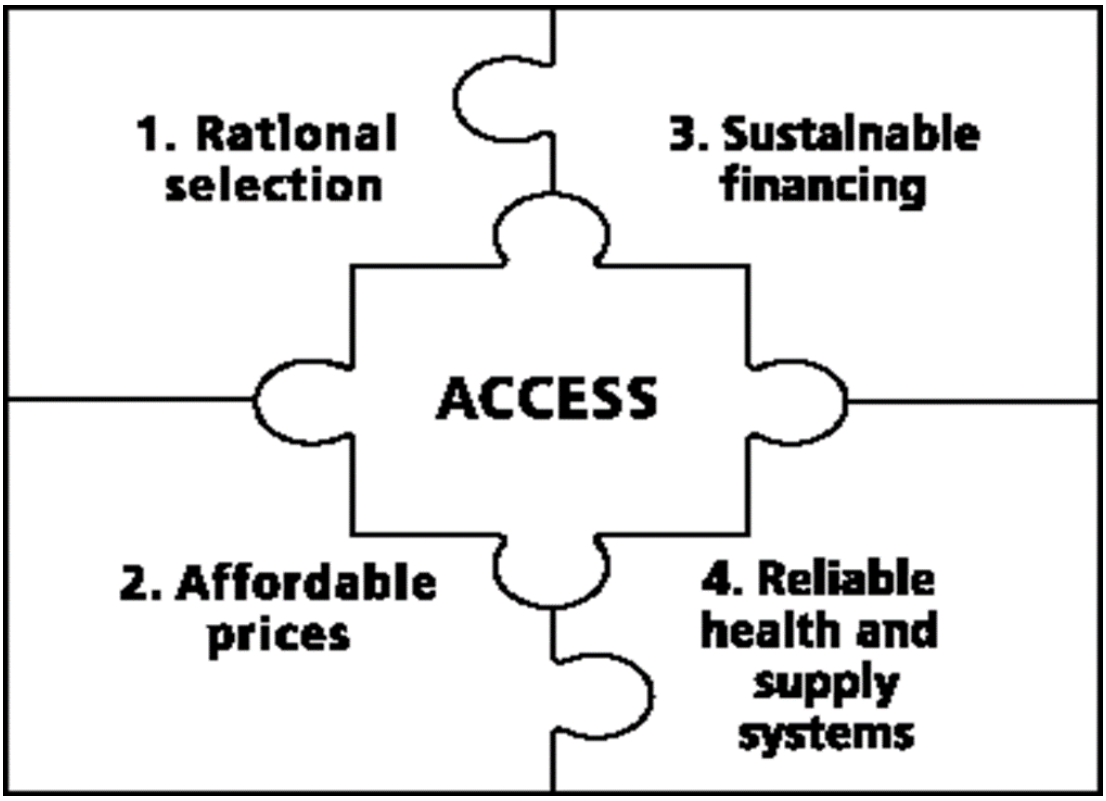


Figure 1: Medicine accessibility framework

The quality of drugs can be achieved through the development and implementation of pharmaceuticals legislations and regulations. Similarly, rational drug use depends on many factors, such as rational selection, regulatory measures, financial factors, prescribers and dispenser factors.

1.2.2 Key strategic components of a national drug policy

A national drug policy is a comprehensive framework in which each component plays an important role in achieving one or more of the general objectives of the policy (access, quality and rational use). The policy should balance the various goals and objectives, creating a complete and consistent entity. For example, access to essential drugs can only be achieved through rational selection, affordable prices, sustainable financing and reliable health and supply systems.

Table 1: Key components of a national drug policy and their relationship with general objectives of the policy

Components of a national drug policy, linked to key policy objectives

Components: \ Objectives:	Access	Quality	Rational use
Selection of essential drugs	X	(X)	X
Affordability	X		
Drug financing	X		
Supply systems	X		(X)
Regulation and quality assurance		X	X
Rational use			X
Research	X	X	X
Human resources	X	X	X
Monitoring and evaluation	X	X	X

X = direct link; (X) = indirect link

A brief account on the various strategic component of an NDP follows:

Selection of essential drugs

Drug selection, preferably linked to national clinical guidelines, is a crucial step in ensuring access to essential drugs and in promoting rational drug use, because no public sector or health insurance system can afford to supply or reimburse all drugs that are available on the market.

Key policy issues are:

- The adoption of the essential drugs concept to identify priorities for government involvement in the pharmaceutical sector, and especially for drug supply in the public sector and for reimbursement schemes;
- Procedures to define and update the national list(s) of essential drugs;
- Selection mechanisms for traditional and herbal medicines

Affordability

Affordable prices are an important prerequisite for ensuring access to essential drugs in the public and private sectors. However, ensuring affordability faces different challenges including:

new pharmaceuticals are usually costly due to patenting; health care in general and pharmaceutical sector in particular is a market failure due to information imbalance between the patient and the provider, externalities ("spill over" benefits) and failure of competition; International trade agreement like the Trade-Related Aspects of Intellectual Property Rights (TRIPS); Industry mergers.

Key policy issues are:

- ✓ Government commitment to ensuring access through increased affordability;
- ✓ For all drugs: reduction of drug taxes, tariffs and distribution margins; pricing policy based on actual costs, benchmark or reference pricing, or direct price negotiation`;
- ✓ For multi-source products: promotion of competition through generic policies, generic substitution and good procurement practices;
- ✓ For single-source products: price negotiations (differential or equity pricing), competition through price information and therapeutic substitution, and TRIPS-compliant measures such as compulsory licensing, "early workings" of patented drugs for generic manufacturers and parallel imports.

Drug financing

Drug financing is another essential component of policies to improve access to essential drugs. The two most important challenges of drug financing are inadequacy of resources to deal with health care demands and the issue of achieving equity of access to drugs. So, financial sustainability requires a balance between demand, the cost of meeting this demand and available resources.

Key policy issues are:

- ✓ commitment to measures to improve efficiency and reduce waste;
- ✓ increased government funding for priority diseases, and the poor and disadvantaged;
- ✓ promotion of drug reimbursement as part of public and private health insurance plan;
- ✓ use and scope of user charges as a (temporary) drug financing option;
- ✓ use of and limits of development loans for drug financing;
- ✓ guidelines for drug donations

Supply systems

The fourth essential component of strategies to increase access to essential drugs is a reliable supply system.

Key policy issues are:

- ✓ Local production
- ✓ public–private mix in drug supply and distribution systems;
- ✓ commitment to good pharmaceutical procurement practices in the public sector;
- ✓ Publishing price information on raw materials and finished products
- ✓ drug supply systems in acute emergencies;
- ✓ Inventory control and prevention of theft and waste;
- ✓ Ensuring Disposal of unwanted or expired drugs

Regulation and quality assurance

The drug regulatory authority is the agency that develops and implements most of the legislation and regulations on pharmaceuticals, to ensure the quality, safety and efficacy of drugs, and the accuracy of product information. This is done by making certain that the manufacture, procurement, import, export, distribution, supply and sale of drugs, product promotion and advertising, and clinical trials are carried out according to specified standards.

Key policy issues are:

- ✓ Government commitment to drug regulation, including the need to ensure a sound legal basis and adequate human and financial resources;
- ✓ Independence and transparency of the drug regulatory agency; relations between the drug regulatory agency and the ministry of health;
- ✓ Stepwise approach to drug evaluation and registration; definition of current and medium-term registration procedures;
- ✓ Commitment to good manufacturing practices (GMP), inspection and law enforcement;
- ✓ Access to drug control facilities;
- ✓ Commitment to regulation of drug promotion;
- ✓ Regulation of traditional and herbal medicines;
- ✓ Need and potential for systems of adverse drug reaction monitoring as a means of ensuring safety;
- ✓ International exchange of information: drug regulatory authorities can exchange information between themselves or with international bodies such as WHO.

Rational use

The rational use of drugs means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Irrational drug use by prescribers and consumers is a very complex problem, which calls for the implementation of many different interventions at the same time. Efforts to promote rational drug use should also cover the use of traditional and herbal medicines. The main challenges in this area are: complexity of the issue, conflicting interests, lack of independent information, inappropriate drug promotion, and unrestricted availability of prescription drugs.

Key policy issues are:

- ✓ Development of evidence-based clinical guidelines, as the basis for training, prescribing, drug utilization review, drug supply and drug reimbursement;
- ✓ Establishment and support of drugs and therapeutics committees;
- ✓ Promotion of the concepts of essential drugs, rational drug use and generic prescribing in basic and in-service training of health professionals;
- ✓ The need and potential for training informal drug sellers;
- ✓ Continuing education of health care providers and independent, unbiased drug information;
- ✓ Consumer education, and ways to deliver it;
- ✓ Financial incentives to promote rational drug use;
- ✓ Regulatory and managerial strategies to promote rational drug use

Research

Operational research facilitates the implementation, monitoring and evaluation of different aspects of drug policy. It is an essential tool in assessing the drug policy‘s impact on national health service systems and delivery, in studying the economics of drug supply, in identifying problems related to prescribing and dispensing, and in understanding the sociocultural aspects of drug use.

Key policy issues are:

- ✓ The need for operational research in drug access, quality and rational use: this is aimed at better understanding of factors affecting drug use and identifying the best methods of selecting, procuring distributing and using drugs;

- ✓ The need and potential for involvement in clinical drug research and development: this involves research into new drugs, new dosage forms and manufacturing processes; research in chemistry and molecular biology and clinical and field trials of drugs and vaccines.

Human resources development

Human resources development includes the policies and strategies chosen to ensure that there are enough trained and motivated personnel available to implement the components of the national drug policy. Lack of motivation and appropriate expertise has been a decisive factor in the failure to achieve national drug policy objectives.

Key policy issues are:

- ✓ Government responsibility for planning and overseeing the development and training of the human resources needed for the pharmaceutical sector;
- ✓ Definition of minimum education and training requirements for each category of staff;
- ✓ Career planning and team building in government service;
- ✓ The need for external assistance (national and international)

Monitoring and evaluation

Monitoring and evaluation are essential components of a national drug policy, and the necessary provisions need to be included in the policy.

Key policy issues are:

- ✓ Explicit government commitment to the principles of monitoring and evaluation;
- ✓ monitoring of the pharmaceutical sector through regular indicator-based surveys;
- ✓ independent external evaluation of the impact of the national drug policy on all sectors of the community and the economy

1.3 Development and implementation of National Drug Policy

1.3.1 Formulating a national drug policy

Overview of the process

A national drug policy involves a complex process of development, implementation and monitoring.

First, the policy development process results in the formulation of the national drug policy. Second, strategies and activities aimed at achieving policy objectives are implemented by the various parties. Finally, the effect of these activities is monitored and the program adjusted if necessary.

Planning

There are various types of plans. The first is probably the strategic plan to develop the policy itself, which should specify the various steps in the development process, and especially plan for the involvement of as many stakeholders as possible. After the policy has been adopted, an implementation plan, or master plan, is needed, which typically covers a 3–5-year period.

Involving all parties

Throughout the policy process (and not only in the development phase) there should be consultation, dialogue and negotiations with all interested groups and stakeholders. These include other ministries (higher education, trade, and industry), doctors, pharmacists and nurses, local and international pharmaceutical industries, drug sellers, academia, NGOs, professional associations and consumer groups. It is also important to consult with provincial and district medical and administrative personnel, and to make an effort to include traditional and herbal medicine practitioners.

Other government agencies (such as the drug regulatory agency), insurance companies and groups paying for health care must be involved. In general it can be said that the more the existing pharmaceutical system needs to be improved, the more important it is to involve all interested parties in discussing the necessary reforms.

Political dynamics

Formulating and implementing a national drug policy are highly political processes. This is because such a policy usually seeks to achieve equity of access to basic health care, primarily by making the pharmaceutical sector more efficient, cost-effective and responsive to health needs.

Such responsiveness may include redistribution of goods and power, leading to increased competition among the groups affected by reform.

Given the diverse interests and the economic importance of the issues involved, opposition to the new policy and attempts to change it during implementation can be expected. For this reason it is important to identify political allies, and to maintain their support throughout the process.

Decisions and priorities touching on the interests of these stakeholders must be balanced on the basis of estimated gains and losses. Strong political leadership and sustained commitment are vital for the formulation and implementation of a national drug policy.

Steps in formulating a national drug policy

Step 1: Organize the policy process

The first step is to decide how to organize the development process that will identify the structure of the policy, its major objectives and its priority components. At this stage it is important to identify all the interested parties that need to be involved, the necessary resources, and how these can be obtained.

Step 2: Identify the main problems

In order to set realistic objectives a thorough analysis and understanding of the main problems in the pharmaceutical sector are needed. There are various ways of carrying out an initial situation analysis. One successful approach has been to bring together a small team of experts, some of whom should have performed similar analyses in other countries. They should be asked to examine the situation systematically, to identify the main problems, to make recommendations about what needs to be done and what can be done, and to identify possible approaches. Once they have formulated their recommendations, these can be discussed at one or more multidisciplinary workshops, in order to formulate consolidated advice to the government.

Step 3: Make a detailed situation analysis

A more detailed situation analysis of the pharmaceutical sector and its components may be needed. This should further analyses the source of the problems, in order to identify potential solutions, choose the most appropriate strategies, set priorities, and serve as a baseline for future systems of monitoring and evaluation.

Step 4: Set goals for a national drug policy

Once the main problems have been defined, goals can be set and priority objectives identified. For instance, if one of the priority problems is lack of access to essential drugs, one of the

priority objectives should be to improve the selection, affordability and distribution of essential drugs.

Step 5: Draft the text of the policy

Once a thorough analysis of the situation and an outline of the main goals, objectives and approaches have been completed, a draft text of the national drug policy should be prepared. It should set out the general objectives of the policy. The specific objectives should also be described, followed in each case by the strategy to be adopted. Drafting of the policy can be done by a small group of experts who have been involved in the earlier stages of the process.

Step 6: Circulate and revise the draft policy

The draft document should be widely circulated for comments, first within the ministry of health, then in other government ministries and departments, and finally to relevant institutions and organizations outside the government, including the private and academic sectors. Once this wide consultation is complete, the draft document should be revised in the light of the comments received, and finalized.

Step 7: Secure formal endorsement of the policy

In some countries the document can then go to the cabinet or parliament for endorsement. In others it will remain an administrative document that serves as a basis for implementation plans and changes in the law and regulations. In some countries the entire national drug policy document has become law. This is a powerful demonstration of political commitment but it can also cause problems, as future adjustments to the policy may become difficult. It is therefore recommended that only certain enabling components of the policy are incorporated into law, without too many operational details.

Step 8: Launch the national drug policy

Introducing a national drug policy is much more than a technical task. To a large extent the policy‘s success will depend on the level of understanding of different sectors of society, and on their support for its objectives. The implications and benefits for all interested parties should therefore be stressed. The policy should be promoted through a clear and well-designed information campaign. Information should be disseminated through a variety of channels to reach different target groups.

1.3.2 Implementing a national drug policy

Learning Activity 1.2

a. Discuss the steps in formulating a national drug policy.

A policy, however carefully formulated, is worthless if it is not implemented. Every drug policy needs an overall implementation plan or ―master plan‖; each component of the policy needs a detailed strategy and specific action plans. Given the multi-sectorial nature of pharmaceutical issue, MOH should develop, as early as possible, the consensus with other government agencies on action plan dealing with specific issue of economics and finance, commerce, industry. The implementation plan allows coordination of donor input and assist in monitoring the policy implementation and intervening when necessary to keep the process moving.

Master plan and work plans

The national drug policy leads to an implementation plan or master plan, which may cover a 3–5 year period. This implementation plan spells out for each component of the policy what needs to be done and who is responsible, estimates the budget requirement and proposes a rough time frame.

Priorities for implementation

For each country the priorities for implementation will be different. For example, when health care coverage is broad and access to drugs is not a problem, rational use and the cost of drugs is likely to be of concern.

Responsibilities in implementation

As lead agency, the ministry of health should oversee and coordinate all activities, and monitor the extent of implementation and the achievement of targets. In some countries a separate unit within the ministry, with its own budget and personnel, acts as the coordinating body. Apart from the coordinating body, it is recommended that a national consultative forum is created to oversee policy implementation.

Financial resources

It is crucial to match the objectives and action plans with the funding that is available. The typical funding sources are allotments from government funds and revenue from drug registration and fee collections. The accountable organizations should be able to obtain recurring funding from the government and should have a system for actively pursuing money. Donations from both international and local contributors are potential sources as well. Accepting donations from donors should not, however, create a conflict of interest, for instance if the donors want to support initiatives that the government's drug policy considers to be low priority.

Regional cooperation

Regional cooperation can be beneficial in the implementation of drug policies. Countries, institutions, and organizations can collaborate to share information, expertise, skills, and resources. Exchanging experiences supports in the promotion of best practices, the avoidance of mistakes, and the efficient use of limited resources.

Countries are increasingly cooperating on a regional level on a wide range of economic and policy issues. Regional partnerships include the Association of Southeast Asian Nations (ASEAN), the European Union (EU), and the Organization of African Unity (OAU).

Successful technological and regulatory collaboration across countries may lead to the harmonization of drug regulatory standards. Harmonization in various sectors could result in the creation of regionally or internationally accepted standards as well as a more efficient use of material, animal, and human resources. However, the matter of sovereignty must be taken into account. Each nation must make sure that the areas being harmonized can be implemented and are pertinent to national interests during the harmonization process.

Technical cooperation with WHO

Through regional and international training programs, cross-national research collaborations, and other means, WHO can act as a forum for information exchange and foster cooperation. Additionally, to training and research, WHO collaborating centers and other centers of excellence are also active in the creation of professional networks and the sharing of information among participating nations.

Strategies to implement national drug policy

- ✓ Countries take different approaches to implementation. A number of strategies are summarized below.
- ✓ Use appropriate timing, and a combination of approaches and methods of implementation.
- ✓ Start implementation in relatively easy –to-change areas to ensure initial high- visibility success.
- ✓ Adopt a flexible policy
- ✓ Use experts to vouch for the policy technical soundness.
- ✓ Mobilize consumer, the media, or other key groups

1.3.3 Monitoring and evaluating a national medicine policy

Monitoring is a form of continuous review that allows senior managers to assess the progress toward achieving defined targets in each policy area and adjust strategies accordingly.

Evaluation is a way of analyzing progress towards meeting objectives and goals.it should build on and use monitoring system. At the starts of a program, evaluation is used to provide a clear assessment of needs. A midterm evaluation can provide valuable information about how well the program is working. Final evaluation allows a complete review of program achievement from which lessons can be drawn for the future.

A system for monitoring and evaluation serves as a management tool that enables continuous assessment of progress and helps officials make management decision in response to problem identified.

Indicators for monitoring national drug policies

Drug policy indicators currently fall into four categories: background data, structural indicators, process indicators, and result indicators. Selected subsets of these metrics may be used to satisfy national needs. A selection of core indicators for routine usage and sentinel reporting has also been agreed upon by WHO and MSH. These indicators are highly standardized, allowing for the detection of patterns. There is a comprehensive instruction on how to use them. Data gathering is very simple, allowing for regular monitoring. The following aspects are covered by core indicators:

- ✓ Access to essential drugs, and other indicators on drug financing schemes, and public supply management; these provide information on access to essential drugs;
- ✓ Functions and efficiency of the drug regulatory authority, the quality control laboratory and how drugs are handled to maintain good quality; these provide information about drug quality;
- ✓ Drug prescribing and dispensing, use of the list of essential drugs and clinical guidelines; these provide information about drug use patterns.

The national drug policy should be evaluated on a regular basis, like every four years. To supplement a national evaluation team, independent consultants or professionals from other countries or WHO may be invited. Such assessments should be a part of the pharmaceutical master plan, with the necessary resources set aside from the start.

1.3.4 The national drug policy of Ethiopia

Objectives

- ✓ To meet the country's demand for essential drugs and to systematize its supply, its supply, distribution and use.
- ✓ To create conducive situations to make the prices of drugs compatible with the people's purchasing power.
- ✓ To ensure the safety, efficacy and quality of drugs.
- ✓ To develop a domestic drug manufacturing capacity and gradual supply to the export market.
- ✓ To expand the training of man power and drugs research' and development.
- ✓ To devise ways and means for the utilization of traditional drugs in the regular health services after ensuring their safety and efficacy.

General policy

- ✓ Determine the types of drugs to be used in the health services on the basis of the country's health problems and capability.
- ✓ Provide essential drugs in line with the responsibilities of the government for public health care.
- ✓ Facilitate the gradual integration of traditional drugs with modern medicine by giving due attention to traditional practices and identifying the beneficial and harmful aspects through investigation and research.
- ✓ Offer incentives to public and private industries involved in the production of raw and packing materials directly related to the manufacture of drugs.
- ✓ Give special incentives to manufacturers who manufacture essential drugs and market them in their generic names.
- ✓ Create favorable conditions to encourage private investors to participate in the manufacture, import and distribution of drugs.
- ✓ Establish an effective system of drug administration and control at all levels, especially by developing the capacity to ensure drug safety, efficacy and quality.
- ✓ Make the necessary efforts to establish rational use of drugs among the health professionals and the public at large.

- ✓ Devise a programme for the training of professionals able to contribute to solving the health problems of the country as required and create conditions for the application and development of their skills.
- ✓ Conduct a coordinated research on modern and traditional drugs attuned to the country's problems and capacity and strive for the application of their results.
- ✓ Create favorable conditions for the transfer and further development of appropriate technology and modern know-how that could assist in meeting the drug needs of the country.
- ✓ Create favorable conditions for the export of local products.
- ✓ Make the necessary efforts to deter the illegal manufacturing, distribution and consumption of narcotics and psychotropic drugs.
- ✓ Strengthen National and International relations to help develop and expand the pharmaceutical sector and give due attention to the implementation of international obligations

1.4 Concept of essential medicines

The Rise of the Concept

Introduction of different medicines like penicillin, Chloroquine, streptomycin, contraceptives, etc. starting from early 1930s revolutionized the field of therapeutics and making the treatment of previously untreatable and fatal diseases possible. This was described as a "Miracle" by some authors in mid 1950s. However, these "Miracles" were unable to reach developing countries. There were later efforts by the developing countries making these miracles accessible to their people though it is limited to urban areas. So the majority the world population was still in the darkness of the lack and inaccessibility of the "miracles". In addition, the already available medicines had very high prices (partly due to protection of products by patents) and were unaffordable to the already constrained economies of the developing world and even some private and public systems in developed countries. From the thousands of high price brand name products that were flooding the market, some were with questionable efficacy and safety (especially those that were going to the predominantly unregulated markets of developing countries). The world's pharmaceutical markets were also witnessing serious disasters from inadequately tested or misused drugs. The cases of Thalidomide related fetal deformation;

Clioquinol induced neurologic disease and dysentery deaths from misuse of Chloramphenicol were notable examples of such disasters.

Recognizing the impact of the above mentioned problems, an idea of working with a limited range of basic and reliable drugs to meet the most vital needs-understanding them, finding ways to pay for them, and supply them to the people emerged. This idea actually is not a new one in that: even in the earlier times doctors learned to carry 20 vital drugs in their bags and ocean going liners commonly carried 100 or fewer. The then poor country Norway started supplying its people with a limited range of affordable drugs to meet basic needs before World War II. This idea propagated to other countries after the war and Papua New Guinea had a policy based on "essential drugs" by the early 1950s; Sri Lanka followed in 1959 (list of 500 drugs), and Cuba had a list of essential drugs by 1963. And other poor countries also followed especially those who were newly gaining their independence from European colonizers. In 1974 the International Labor Office adopted the idea of defining and meeting "basic needs" in the developing world; at the same time, the WHO director general proclaimed a new policy aimed at improving the health of rural and peri-urban populations. In 1975, he defined essential drugs as "*those considered to be of utmost importance and hence basic, indispensable, and necessary for the health needs of the population. They should be available at all times, in the proper dosage forms, to all segments of society*." A year later, the World Health Organization (WHO) prepared its first *Model List of Essential Drugs*, listing 224 drugs and vaccines. In Alma Ata in 1978, the WHO/UNICEF Conference on Primary Health Care adopted the essential drugs concept as one of its basic tools. In Geneva, the Division of Drug Policy and Management came into being to develop the concept as part of national drug policy for member states. There was also important backing from an interagency task force set up by the United Nations (UN), which by 1979 recommended the adoption of national drug lists using generic names.

The Concept

After immunization for common childhood illnesses, appropriate use of essential medicines is one of the most cost-effective components of modern health care. The World Health Organization has defined essential medicines as those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the

appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility. The selection of essential medicines is one of the core principles of a national drug policy because it helps to set priorities for all aspects of the pharmaceutical system.

Careful selection of a limited range of essential medicines has several advantages on the supply, prescribing, cost and patient use of medicines. Numerous studies have documented the impact of clinical guidelines and lists of essential medicines on the availability and proper use of medicines within health care systems. All of this is even more important in resource-poor settings where the availability of drugs in the public sector is often erratic. Under such circumstances measures to ensure a regular supply of essential medicines will result in real health gains and in increased public confidence in the health services. Among the advantages of essential medicines concepts on supply of medicines are:

- ✓ Easier procurement, storage, and distribution
- ✓ Lower stocks
- ✓ Better quality assurance
- ✓ Easier dispensing

Advantages on prescribing:

- ✓ Training more focused and therefore easier
- ✓ More experience with fewer drugs
- ✓ No irrational treatment alternative available
- ✓ Focused drug information
- ✓ Better recognition of adverse drug reactions

Impact on cost:

- ✓ Lower prices, more competition

Advantages on Patient Use:

- ✓ Focused education efforts
- ✓ Reduced confusion and increased adherence to treatment
- ✓ Improved drug availability

The essential medicines concept is a global concept which can be applied in any country, in private and public sectors and at different levels of the health care system. No public sector or health insurance system can afford to supply or reimburse all medicines that are available on the market. Essential medicines are not cheap medicines for poor people in rural areas in developing countries; they are the most cost effective treatment for a given condition. Lists of essential medicines provide the scientific and public health basis for focus and expenditure in the pharmaceutical sector. So the essential drugs concept is applicable even in the developed countries. And that is why many people and insurance companies advocate the essential drugs concept in the developed countries settings.

Learning Activity 1.3.

a. Reviewing the historical development of essential medicines, what was the motive behind the concept of essential medicines?

1.5 Formulary process

Once a national essential drugs list has been agreed upon and adopted, the next step is the development of standard treatment guidelines and a formulary manual. Before we proceed it is better to be clear with the definitions of some terms. Essential Drug List: is a list of drugs considered optimal treatment choices to satisfy the health care needs of a given population. It can be used for a given health facility, or for a group of health facilities to indicate which drugs should be procured and prescribed. Formulary List: is a list of drug products approved for use in a specific health care setting. It may be a national formulary list, a provincial list, a hospital list, or a list reimbursed by a health insurance program. In most of the cases, formulary list is synonymous with essential drugs list. Standard Treatment Guidelines (also called: treatment guidelines or protocols) are systematically developed statements that assist prescribers in deciding on appropriate treatments for specific clinical problems. A Formulary Manual is a summary of drug information. It is a handy reference that contains selected information that is relevant to the prescriber, dispenser, nurse or other health worker. It commonly includes the generic name of a drug, its indications for use, dosage schedules, contraindications, side effects, and important information that should be given to the patient. And the system that encompasses

the whole system for developing, updating, and promoting the formulary list or EDL is known as the Formulary System.

The procedures to develop an essential drug list, a set of STGs or a formulary manual are similar, together they could be called the formulary process. The most logical approach in the formulary process is based on the needs of patient sand on the job descriptions of health workers. The first step is to prepare a list of common health problems. A first choice treatment for each health problem on the list may be limited to one or more drugs or to various forms of non-drug treatment. This choice of treatment can be the basis for two important documents: the list of essential drugs for that level of care, which is a direct result of the selection; and a set of treatment guidelines for that level of care, which requires additional clinical information (diagnostic signs and symptoms and treatment algorithms). The lists of essential drugs for each level of care should be combined into one national list of essential drugs. This list is the basis for developing the national formulary. This approach ensures that the supply of drugs, which is based on the national list of essential drugs, is consistent with the treatment guidelines in public sector facilities and training institutions and that summary drug information is available for all drugs supplied in the public sector.

Drug selection by committee is the recommended approach in that it minimizes the opportunity for private interests to influence the decision-making process and rational selection of drugs can be assured. At national level selection can be done by an officially appointed committee and the drug and therapeutics committee in individual hospitals. Members of the committee are preferred to be from different backgrounds and they should be known for their integrity, honesty, and dedication; ideally they should not have relations with any drug manufacturer or distributor, nor be closely related to any person who does. Technical experts committee in the selection of drugs should include one or more clinical pharmacologists, an internist, an infectious disease specialist, a pediatrician, a surgeon, one or more hospital and district pharmacists, a hospital director and other specialists as needed. Representatives of disease control programs can be co-opted to attend certain meetings. Committee members should serve for several years with staggered terms, so that the committee retains some experienced members each year. A pictorial representation of the formulary process is presented in figure 2.

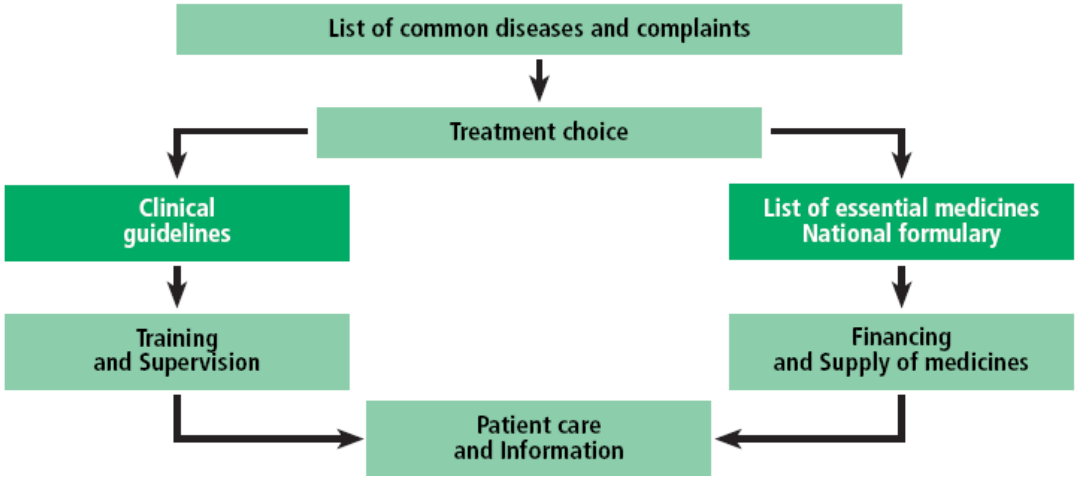

List of common diseases and complaints
Treatment choice
Clinical guidelines
List of essential medicines National formulary
Training and Supervision
Financing and Supply of medicines
Patient care and Information

Figure 2: The Formulary Process

Source: WHO Policy Perspectives on Medicines; the Selection of Essential Medicines

The procedure for developing an **essential medicine list, a set of treatment guidelines, and a formulary manual** are all similar; together they can be called the formulary process.

1.5.1 Treatment guidelines

The standard treatment guidelines are used to indicate systematically developed statements that help practitioner or prescriber make decision about appropriate treatment for specific clinical conditions.

- ✓ Treatment Guidelines (Standard Treatment Guidelines)[STGs],treatment protocols, clinical guidelines are systematically developed statements that assist prescribers in deciding on appropriate treatments for specific clinical problems
- ✓ Reflects the consensus on the optimal treatment options within a health facility or health system
- ✓ The information is disease-centered, emphasizing the common diseases & complaints & the various treatment alternatives
- ✓ Information on medicines is usually limited to strength, dosage, & duration.
- ✓ Most guidelines indicate a treatment of first choice
- ✓ Some include diagnostic criteria for starting the treatment or for choosing among treatment alternatives

- ✓ The key differences between formulary manual & TGs is that the former is drug-centered, concentrating on drug information & usually not providing comparisons of different medicines, whereas the latter are disease-centered, listing treatment alternatives and indicating treatments of choice.

Potential benefit of standard treatment guidelines

For health staff

- ✓ Provide identification of cost- effective treatments for common health problems.
- ✓ Provides basis for assessing and comparing quality of care.
- ✓ Identifies most effective therapy in terms of quality and combat antimicrobial resistance

For supply management staff

- ✓ Identifies which medicines should be available for the most commonly treated problems
- ✓ Makes medicine demand more predictable, so for-casting is more reliable

For health care provider

- ✓ Provide expert consensus on most effective, economical treatment for a specific setting
- ✓ Give the provider the opportunity to concentrate on correct diagnosis.
- ✓ Set a quality-of-care standard
- ✓ Provide basis for monitoring and supervision

For patients

- ✓ Encourages adherence to treatment through consistency among prescriber at all locations within the health care systems guidelines.
- ✓ Improve treatment and outcomes.

Development of standard treatment guidelines

In developing standard treatment guidelines, the starting point is a list of common disease and compliant. Next, the standard treatment of choice is defined for each diagnosis or problem. The process of developing treatment guidelines is similar to that of developing an essential medicine list or formulary manual, and only those aspects specific to treating guidelines are discussed here.

The process involves:-

- ✓ Establishment of a guidelines development committee
- ✓ Targeting different level of care
- ✓ Identifying and assessing the clinical evidence

- ✓ Drafting the guidelines
- ✓ Reviewing and editing the draft

Information in treatment guidelines

Treatment guidelines are disease oriented. This focus means that the treatment of choice is presented for each common heath problem, together with the basic information needed by the prescriber.

- ✓ Diagnostic criteria
- ✓ Treatment of first choice
- ✓ Important contraindication and side effects
- ✓ Important drug information, warnings, and precautions
- ✓ Referral criteria

1.5.2 Formulary manual

A formulary manual contains summary information on a selected number of medicines. It is a drug centered, and the information is usually organized in the therapeutic groups. In most developing countries, the national formulary list is limited to medicines on the national list of essential medicine. Although there are several available reference texts that include comprehensive drug information, they may not be appropriate for all settings. A national formulary manual concentrates on medications relevant to a particular country.

Information in a formulary manual

The information is usually presented in the form of drug information sheets or drug monographs.

Basic information for each drug

- ✓ Generic name or brand names
- ✓ Dosage forms and strength
- ✓ Main indication
- ✓ Pharmacological data including pharmacokinetic data and contraindication
- ✓ Precautions (such as pregnancy, breast feeding, etc)
- ✓ Side effects (major and minor, with estimated frequency)
- ✓ Dosage schedule (dosage forms, frequency, duration, pediatric dosage, dosage adjustments for the elderly and for those with renal or liver problems.
- ✓ Instruction and warnings
- ✓ Drug, food, lab interactions

Supplementary information on each drug

- ✓ Regulatory category (prescription only, over the counter, controlled narcotic drugs)
- ✓ Storage guidelines
- ✓ Patient counseling information, Labeling information

Prescribing and dispensing guidelines

- ✓ Rational prescribing
- ✓ Principles of prescription writing
- ✓ Use of placebo
- ✓ Special requirements for inpatient prescription
- ✓ Guidelines on quantities to be supplied
- ✓ Special requirements for controlled drug prescriptions
- ✓ Prevention and reporting of adverse drug reaction, etc

General drug use advice

- ✓ Use of intravenous additives
- ✓ Prescribing in special situation
- ✓ Poisoning

Developing a formulary manual

The process of developing a formulary manual is much similar with the process of developing of EDL and treatment guideline

The process involves:-

- ✓ Establish a national formulary committee
- ✓ Secure agreement on the content, structure, and format the formulary
- ✓ Appoint an editor
- ✓ Review the draft
- ✓ Revise and produce new editions

Learning activity 1.4.

a. List at least three differences between formulary manual and standard treatment guidelines?

1.6 Pharmaceutical Sector Transformation Plan of Ethiopia

Cognizant of the pivotal role of pharmaceuticals and other health care technologies, the GoE established an agency called Pharmaceutical Fund and Supply Agency (PFSA) and the supply management of pharmaceuticals in the country has shown significant progress especially during HSDP IV. The Integrated Pharmaceuticals Logistics System (IPLS) was implemented in 2010 to integrate the supply management of pharmaceuticals and the Revolving Drug Fund (RDF). At each level, the system provides accurate and timely data for decision-making where product related information flows up from health facilities to the Agency whereas products flow from the Agency down to health facilities every two months. Routine monitoring reports show that IPLS is improving information recording and reporting, storage and distribution systems, as well as the availability of essential commodities at service delivery points (SDPs). The national survey conducted in January 2014 on IPLS to measure system performance at public health facilities (hospitals, health centers and health posts) indicated that the system significantly improved the availability of essential pharmaceuticals at health facilities. The average availability of essential tracer medicines at health facilities on the day of visit was 89%. The Agency's target for HSDP IV in this regard was to increase the availability of essential pharmaceuticals from 65% to 100%. Average availability of the tracer pharmaceuticals during six months prior to the study was 78.1%. This is an indication of the improvement in the availability of essential pharmaceuticals at public health facilities providing primary and secondary level of care. After completion of HSDP IV in 2019/2020, the government prepared HSTP II for 5 years (2020/2021-2024/2025).

The strategic direction of HSTP II regarding pharmaceutical sector focuses on the following areas:

- ✓ Prevention and Containment of Anti-Microbial Resistance (AMR)
- ✓ Improve access to pharmaceuticals and medical devices and their rational and proper use
- ✓ Improve regulatory systems
- ✓ Improve human resource development and management

1. **Prevention and Containment of Anti-Microbial Resistance (AMR)**

   Evidences have shown that Antimicrobial Resistance (AMR) is becoming a global health and development threat.

   AMR is found not only among pathogens that cause common bacterial infections, but also in diseases such as TB, HIV, Malaria and fungal infections. AMR leads to prolonged illness,

longer hospital stays, higher medical costs and increased mortality. It also threatens to undermine the effectiveness of health programs and reduce public confidence.

Major strategic initiatives

- ✓ Improve awareness and understanding of antimicrobial resistance through effective communication, education and training. Strengthen AMR training in Continuous Professional Development and pre-service training
- ✓ Strengthen knowledge and evidence through surveillance and research
- ✓ Optimize the use of antimicrobials and ensure optimal prescribing, dispensing and use.
- ✓ Improve access to quality antimicrobials and laboratory commodities and initiate DST in public and private hospitals.
- ✓ Strengthen leadership, ownership, and commitment for implementation of AMR prevention and containment activities at national, regional/city administration, and health facility level.
- ✓ Improve infection prevention and contain the spread of resistant microorganisms across human and animal communities and health care settings through individual and environmental sanitation, hygiene, and infection prevention measures

2. Improve access to pharmaceuticals and medical devices, and their rational and proper use

This strategic direction focuses on:

- ✓ Strengthening the pharmaceutical supply chain, pharmacy services, and medical device management systems to ensure uninterrupted availability and accessibility of safe, effective, and affordable medicines and medical devices that are needed to address the health problems
- ✓ Reduction of pharmaceutical wastage and strengthening of systematic and environmentally friendly disposal of expired and damaged pharmaceuticals and non-functional medical devices.
- ✓ Strengthen local manufacturing of medicines and medical devices, and standardization of procedures for procurement and management of medical devices.
- ✓ **Major strategic initiatives**

- ✓ Strengthen Strategic Procurement System through the introduction of e-procurement, establishment of international and regional pooled procurement, and long-term fixed price procurement mechanisms
- ✓ Develop medicine selection, pricing and reimbursement strategy
- ✓ Establish Central Order Management System
- ✓ Develop and implement demand-based forecasting and supply planning
- ✓ Establish market shaping strategies for pharmaceuticals and medical devices
- ✓ Optimize good warehousing, inventory, fleet and distribution practice
- ✓ Establish end-to-end data visibility for the supply management of medicines and medical devices such as implementation of track and trace system
- ✓ Establish and implement track and trace system for medicines and medical devices across the supply chain
- ✓ Strengthen medical device management system such as standardization of medical device, maintenance workshops, refurbishment centers , maintenance referral system and disposal
- ✓ Implement reverse logistics at health facilities and pharmacy retail outlets that extends to households
- ✓ Develop and implement strategies to reduce medicine wastage and to implement pharmaceuticals waste management and medical devices decommissioning
- ✓ Strengthen capacity for local manufacturing of medicines and medical devices
- ✓ Establish National Medicine and Poison Information Center
- ✓ Strengthen the prevention and containment of antimicrobial resistance
- ✓ Strengthen implementation of auditable pharmaceutical transactions and services
- ✓ Strengthen clinical pharmacy and drug information services
- ✓ Revise the National Medicine Policy
- ✓ Strengthen integration of modern and traditional medicine
- ✓ Introduce audit-and-feedback and accountability system at all levels

3. Improve Regulatory Systems

This strategic direction seeks to protect the public from health risks that arise from poor and substandard products and services.

It focuses on ensuring the safety, quality, efficacy, and proper use of medicines; performance of medical devices; safety of food; quality of health and health-related services against standards; competence of health professionals; and regulation of tobacco and alcohol.

It also includes the implementation of digital regulation systems to establish an effective, transparent, and accountable system that ensures adherence by all state and non-state actors to national health regulatory standards and legal frameworks.

Major strategic initiatives

Regulation of Food, Medicines, Equipment, and Other Health Products

- ✓ Build and maintain adequate quality control systems, infrastructures, and laboratories (including Min-laboratories at each entry and exit port)
- ✓ Control food adulteration and develop a rapid alert system for health products
- ✓ Strengthen registration capacity, introduce product- and risk-based auditing pre- and post-licensing inspection, improve post-shipment (consignment) and post-marketing surveillance, and enforce quality control tests of products
- ✓ Strengthen pharmaco-vigilance and vaccine safety and improve interface with clinical surveillance
- ✓ Establish a regulatory system for safety and quality of blood, blood products, human tissues, and organs
- ✓ Establish Regulatory Center of Excellence to provide service, training, and research
- ✓ Standardize, register, and regulate the safety and efficacy of traditional medicine and practice

Regulation of Health Professionals and Health and Health-Related Facilities

- ✓ Regulation of health professionals and traditional medicine practitioners (professional ethics and code of conduct)
- ✓ Regulation of health and health-related facilities, both public and private (enforcing adherence to the Ethiopian health facility minimum standard)
- ✓ Competency assessment of all graduates before joining the health workforce
- ✓ Introduce and scale up clinical audits to ensure quality of practice in health facilities
- ✓ Engage private health care facility associations in health regulatory system

4. Improve Human Resource Development and Management

This direction entails human resources planning, development and management (training, capacity building, recruitment, deployment, performance management, and motivation) to ensure the presence of motivated, competent, compassionate and committed health professionals in adequate numbers and skill mix. It focuses on improving the quality of pre-service training and continuous professional development, and will emphasize promotion of ethics and professionalism in pre-service education and in-service training programs. The human resource management aspect of this direction focuses on need-based training, recruitment, deployment, performance management, and motivation.

Major strategic initiatives

- ✓ Strengthen system of compassionate, competent, and motivated health workforce through quality pre-service education, improved retention and motivation mechanism, continuous professional development (CPD) integrated with professional re-licensing
- ✓ Strengthen health facility-based education and training in the health system, and also make health facilities conducive to health science training
- ✓ Enhance demand driven-health workforce forecasting, planning, and development
- ✓ Establish health professionals council and engagement of health care workers
- ✓ Integrate academic activities, service provision, and research functions at teaching hospitals
- ✓ Redesign health workforce intake approaches through joint education-health planning and integration mechanisms
- ✓ Develop and implement strategies to enhance health workforce safety
- ✓ Shift HEW career levels to a level IV and above, and improve career structure of the health workforce in general
- ✓ Ensure the distribution and availability of health workforce to health facilities with adequate number and appropriate professional and gender mix in an equitable manner
- ✓ Establish National Health Workforce Accounts and national Health Workforce Observatory
- ✓ Conduct provider competency assessment survey on a yearly basis

Chapter 2: Essentials of Pharmaceutical Supply Chain Management

This chapter focuses on the concepts of pharmaceuticals supply chain management and some supply chain-related key terminologies. It also discusses pharmaceutical logistics and key components of logistics system. Besides, the importance and integrity of the supply chain to global health, and developing healthcare supply chain maps are addressed.

Upon completion of this chapter, the students will be able to:

- ✓ Define pharmaceuticals supply chain management
- ✓ Define logistics and Key Logistics terms
- ✓ Describe the importance of logistics for all health programs
- ✓ Discuss purpose of a logistics system
- ✓ Differentiate different components of a logistics system
- ✓ Define key Supply Chain and terminologies and Concepts
- ✓ Describe how to develop pharmaceutical Supply Chain Maps
- ✓ Explain the impact of globalization on pharmaceuticals supply chains
- ✓ Discuss the importance and integrity of the supply chain to global health

2.1 What is Pharmaceutical Supply chain Management?

Supply chain: A supply chain refers to products, services, finances, and information flowing from a supplying organization to end users. It can also be defined as a system of organizations, people, activities, information, and resources involved in moving a product or service from supplier to end-users.

Logistics: Logistics refer to what happens within an organization while purchasing and materials from suppliers to distributors to end-users.

Supply chain management is defined as "the integration of key business processes from end-users through original suppliers that provide products, services, and information and add value for customers and other stakeholders". Importantly, it also includes coordination and collaboration with channel partners, which can be suppliers, intermediaries, third party service providers, and customers. In essence, supply chain management integrates supply and demand management within and across companies.

Definition of pharmaceuticals…. To be added…

Pharmaceuticals supply chain management

Pharmaceuticals supply chain management is the management of health products and information flow in a supply chain system at a value-for-money cost to provide adequate, appropriate supplies to patients.

Supply Chain Management can be viewed as the active management of supply chain activities to maximize customer value and achieve a sustainable competitive advantage. In simple terms it is the coordination of production, inventory, location and transportation among the participants in a supply chain to achieve the best mix of responsiveness and efficiency for the market being served. The concept of Supply Chain Management is based on two core ideas. The first is that practically every product that reaches an end user represents the cumulative effort of multiple organizations. These organizations are referred to collectively as the supply chain. A supply chain is the alignment of firms that bring products or services to market. It includes not only the manufacturer and suppliers, but also includes transporters, warehouses, retailers, and customers themselves.

The second idea is that supply chain management involves the active management of supply chain activities to maximize customer value and achieve a sustainable competitive advantage. It

represents a conscious effort by the supply chain firms to develop and run supply chains in the most effective & efficient ways possible. Supply chain activities cover everything from product development, sourcing, production, and logistics, as well as the information systems needed to coordinate these activities. The organizations that make up the supply chain are "linked" together through physical flows and information flows. Physical flows involve the transformation, movement, and storage of goods and materials. They are the most visible piece of the supply chain. But just as important are information flows. Information flows allow the various supply chain partners to coordinate their long-term plans, and to control the day-to-day flow of goods and material up and down the supply chain.

Learning Activity 2.1.

a. What is the difference between supply chain management and logistics?

b. What makes pharmaceutical supply chain different from other products supply chain? Can you identify some products that might have similar characteristics with pharmaceutical supply chain?

2.2 Key Supply Chain Terminology and Concepts

Value: Since the ultimate goal of supply chain management is to serve the customer better by creating or adding value, supply chain management begins with the understanding of customer values and requirements. Generally speaking, "value is the amount customers are willing to pay for what an organization provides them and thus is measured by total revenue, a reflection of the price an organization's product and service commands and the units it can sell" (Porter 1985). Thus, the extent of value created and added by the organization dictates its level of success, because the higher the value, the greater the customer satisfaction and competitive advantages.

Value Chain: The value chain begins with new product development, which creates specifications for the product. Marketing and sales generate demand by publicizing the customer priorities that the products and services will satisfy. Marketing also brings customer input back to new product development. Using a new product specifications, operations transforms inputs to outputs to create the product. Distribution either takes the product to the customer or brings the customer to the product. Service responds to customer requests during or after the sale. These are

core processes or functions that must be performed for a successful sale. Finance, accounting, information technology, and human resources support and facilitate the functioning of the value chain.

Push Versus pull strategy: Placing orders is a routine activity in logistics. In most logistics systems, an order is placed for new supplies every month or every quarter. In some logistics systems, the quantity to be ordered is determined by the person placing the order. This is called a pull or requisition system. In other systems, the quantity to be ordered is determined by the person who fulfills the order. This is called a push or allocation system.

Postponement strategy: Postponement is first implemented in manufacturing processes to reduce cost of inventory and improve service level within the company while the product variety increases. The concept of postponement is to delay the change in form, identity and place to the latest possible point until customer commitments have been obtained. It is by exploiting the commonality between items and by designing the production and distribution process so as to delay the point of differentiation. Postponement is closely intertwined with modularization where products in a certain product family are designed where all of them consist of different standardized units. With modularization, combination of different standardized sub-components allows the producing of different end products. The form, function and place of the product are altered and is in contra with the push systems in which goods are manufactured entirely in anticipation of future customer orders and stored downstream without customer's formulated specifications.

Bullwhip effect: The bullwhip effect is a supply chain phenomenon describing how small fluctuations in demand at the retail level can cause progressively larger fluctuations in demand at the wholesale, distributor, manufacturer, and raw material supplier levels. The effect is named after the physics involved in cracking a whip.

Strategic alliance: A strategic alliance is an arrangement between two companies to undertake a mutually beneficial project while each retains its independence. The agreement is less complex and less binding than a joint venture, in which two businesses pool resources to create a separate business entity.

Core Competency: The core competencies in business (supply chain), also known as *distinctive competencies*, refer to its resources and unique fundamental capabilities that distinguish it from market competitors and give it competitive advantage. It is an essential component of marketing

strategy leading to brand recognition and business growth. The concept serves to be useful for organization working on healthcare (pharmaceutical supply chain business.

2.3 Logistics Management

Logistics is part of supply chain management that plans, implements, and controls the efficient, effective forward and reverses flow and storage of goods, services and related information between the point of origin and the point of consumption in order to meet customers' requirement. It is basically a process of transporting goods (either raw material or finished products) from one point to another point. The two major functions of logistics are transportation and warehousing. It is an integrating function, which coordinates and optimizes all logistics activities, as well as integrates logistics activities with other functions including marketing, sales manufacturing, finance, and information technology

Difference between Inbound and Outbound Logistics

✓ Logistics activities include inbound logistics or outbound logistics

Inbound logistics refers to the sourcing, expediting and receiving of goods that is coming to the business organization.

Outbound logistics is all about warehousing, packaging and transporting of goods, going out of the organization.

Table 2: Comparison of Inbound Logistics and Outbound Logistics

Basis for comparison	Inbound logistics	Outbound logistics
Meaning	The influx of raw material and parts, from suppliers to the manufacturing plant, is known as inbound logistics	The outward movement of final goods, from the company to the end user, is known as outbound logistics.
Related to	Material management and procurement	Customer service and channel of distribution
Focuses	Deployment of resources and raw materials, within the manufacturing plant	Movement of finished goods or product from the business to the final customer
Interaction	Between the supplier and the firm	Between the firm and customers

Summary of Inbound Logistics

- Inbound logistics connotes the activities which are related to sourcing, acquiring, storing and delivering the raw materials and parts to the product or service department. It is part and parcel of the operations, for a firm involved in manufacturing business.
- In simple terms, inbound logistics is the fundamental activity, which focuses on buying and scheduling the inflow of materials, tools and final goods, from suppliers to the production unit, warehouse or retail store**.**

Summary of out bound Logistics

- Outbound logistics, as the name suggests, is the collection, storage and distribution of the final goods and related information flows, from the manufacturing plant to the end user. It covers all those activities (i.e. selecting, organizing, transporting, etc.) which are involved in the outflow of merchandise from seller to the buyer.

Learning activity 2.2.

1. Classify the following logistics activities as inbound and outbound logistics

    a. Receiving
    b. Last-mile Delivery
    c. Ordering/purchasing
    d. Delivery Optimization
    e. Sourcing and procurement

2.4 Why is logistics important for all health programs?

Effective supply chains not only help ensure commodity security, they also help determine the success or failure of any public health program. Both in business and in the public sector, decision makers increasingly direct their attention to improving supply chains, because logistics improvements bring important, quantifiable benefits. Well-functioning supply chains benefit public health programs in important ways by:

- ✓ Increasing program impact
- ✓ Enhancing quality of care
- ✓ Improving cost effectiveness and efficiency.

Logistics increases program impact

If a logistics system provides a reliable supply of commodities, more people are likely to use health services. Customers feel more confident about the health program when they have a constant supply of commodities. Health programs cannot succeed unless the supply chain delivers a reliable, continuous supply of health commodities to its customers.

No product? No program!

Logistics enhances quality of care

Well-supplied health programs can provide superior service, while poorly supplied programs cannot. Likewise, well-supplied health workers can use their training and expertise fully, directly improving the quality of care for clients. Customers are not the only ones who benefit from the consistent availability of commodities. An effective logistics system helps provide adequate, appropriate supplies to health providers, increasing their professional satisfaction, motivation, and morale. Motivated staffs are more likely to deliver a higher quality of service.

Logistics improves cost efficiency and effectiveness

An effective supply chain contributes to improved cost effectiveness in all parts of a program, and it can stretch limited resources. Strengthening and maintaining the logistics system is an investment that pays off in three ways. (1) It reduces losses due to overstock, waste, expiry, damage, pilferage, and inefficiency; (2) it protects other major program investments; and (3) it maximizes the potential for cost recovery.

The purpose of logistics system

- Ensures the fulfilment of the Six Rights of Logistics:

The RIGHT goods

In the RIGHT quantities

In the RIGHT condition

Delivered…

To the RIGHT place

At the RIGHT time

For the RIGHT cost

2.5 Major components and activities of Logistics cycle

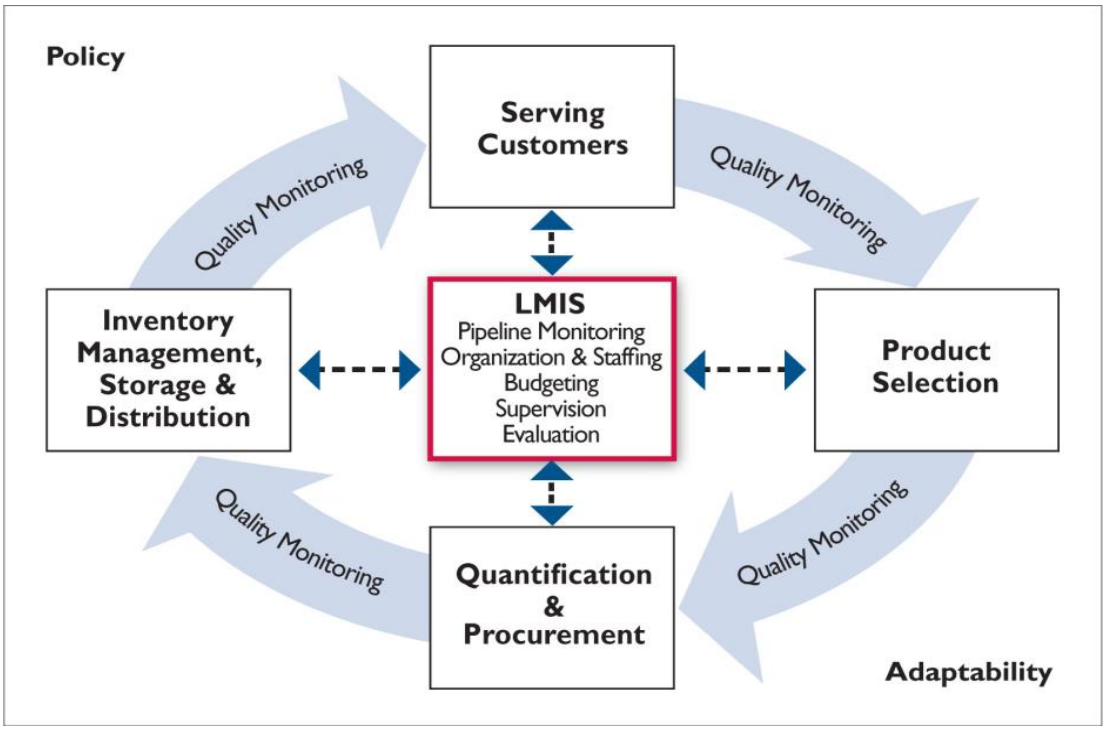


Figure 3: Logistics Cycle: Organizing Logistics System Activities that support six Rights
Source: USAID/DELIVER PROJECT, logistics handbook, 2011

Major activities in the logistics cycle

Let's briefly review the major activities in the logistics cycle:

Serving customers: Everyone who works in logistics must remember that they select, procure, store, or distribute products to meet customer needs. Storekeepers do not store drugs just for the purpose of storing; they store products to ensure that commodity security exists for every customer to obtain and use the health commodities when they need them. In addition to serving the needs of the end customer, the customer seeking health services—each person in the process is also serving the needs of more immediate customers. Storekeepers provide customer service when they issue medicines to the health facility, and the central medical stores provide customer service when they issue commodities to the district. The logistics system ensures customer service by fulfilling the six rights. Each activity in the logistics cycle, therefore, contributes to excellent customer service and to ensuring commodity security.

Product selection: In any health logistics system, health programs must select products. In a health logistics system, a national formulary and therapeutics committee, pharmaceutical board, board of physicians, or other government-appointed group may be responsible for product selection. Most countries have developed essential medicine lists patterned on the World Health Organization (WHO) Model List. Products selected for use will impact the logistics system, so the logistics requirements must be considered during the product selection.

Quantification: After products have been selected, the required quantity and cost of each product must be determined. Quantification is the process of estimating the quantity and cost of the products required for a specific health program (or service), and, to ensure an uninterrupted supply for the program, determining when the products should be procured and distributed. See the suggested reading list at the end of the handbook for sources of additional information about quantification of health commodities.

Procurement: After a supply plan has been developed as part of the quantification process, quantities of products must be procured. Health systems or programs can procure from international, regional, or local sources of supply; or they can use a procurement agent for this logistics activity. In any case, procurement should follow a set of specific procedures that ensure an open and transparent process that supports the six rights.

Inventory management, storage and distribution: After an item has been procured and received by the health system or program, it must be transported to the service delivery level where the client will receive the products. During this process, the products must be stored until they are sent to the next lower level, or until the customer needs them. Almost all businesses store a quantity of stock for future customer needs.

Heart of the logistics system

Information is the engine that drives the logistics cycle; without information, the logistics system would not run smoothly.

Logistics management information systems: In the beginning of the cycle, managers gather information about each activity in the system and analyze that information to make decisions and coordinate future actions. For example, information about product consumption and inventory levels must be gathered to ensure that a manager knows how much of a product to procure.

Logisticians added the word logistics to management information system (MIS) to create logistics management information system (LMIS). Logisticians want it clear that the collection

of data for managing a logistics system is a separate activity from the collection of data for other information systems, including health management information systems (HMISs). An LMIS collects data about commodities; this information is often used for activities, such as filling routine supply orders for health facilities. An HMIS collects information on the total number of patients seen or diagnosed; data from an HMIS is not used as often as LMIS data— i.e., annually—and it is used for different purposes—i.e., for evaluating program impact. Logisticians emphasize the use of logistics data for making decisions about activities within the logistics cycle.

2.6 Key Logistics Terms

Supplies, commodities, goods, materials, products, and stock: These items flow through a logistics system.

Users, clients, patients, and customers: The people who receive or use supplies.

Users: is familiar to anyone who collects information about new or continuing users. Users can also refer to people who use a product that is not given to a client or patient but is used for them, such as an HIV test kit or a laboratory reagent.

Clients: usually refers to someone who receives a treatment or service. For example, they could be a family planning client and receive contraceptives; or they could be a client and receive a service, such as a test for malaria or TB.

Patients: is a term often associated with clinic patients receiving treatment for an illness, such as those in an antiretroviral therapy (ART) program.

Customers: is a term typically used by the private sector; it helps reinforce the concept of customer service. In public health programs, all users, clients, and patients are considered to be customers in the same way a commercial business thinks of its customers: the service provider, health centre, and laboratory are there to serve the customer. The concept of customer service can also be applied between levels of a logistics system, the regional or provincial warehouse is the customer of the central warehouse.

Consumption, dispensed, dispensed to user, usage data: Data on the quantity of goods given to or used by customers.

Service delivery point: Any facility where users receive supplies related to health services. Service delivery points (SDPs) are usually hospitals and health centers, but may also include mobile units, community-based distributors, laboratories, and health posts.

Pipeline: The entire chain of physical storage facilities and transportation links through which supplies move from the manufacturer to the user, including port facilities, central warehouse, regional warehouses, district warehouses, all SDPs, and transport vehicles, including community-based distribution networks.

Lead time: The time between when new stock is ordered and when it is received and available for use. When logistics managers evaluate how well a logistics system is meeting the six rights, they measure the lead time and try to reduce it. Goods should be available to customers at the right time—before the customer asks for the product. Lead time can be calculated within the entire in-country system, from arrival in port to the end user, between specific levels of the system, or even the procurement lead time from when a product is ordered with the manufacturer until it arrives in port.

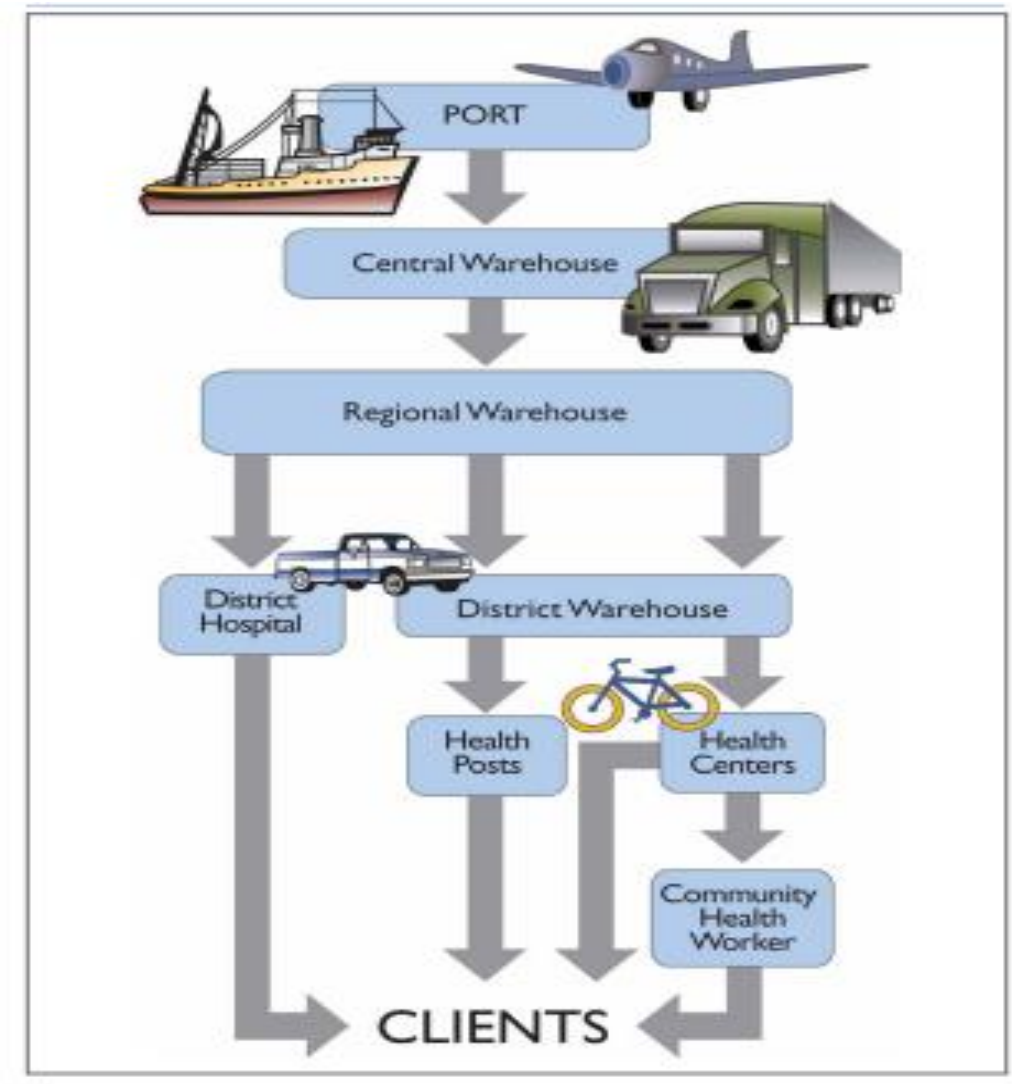


Figure 3: Typical public sector in-country supply pipeline

Adopted from USAID/DELIVER PROJECT, logistics handbook, 2011

2.7 The importance and integrity of the supply chain to global health

There is an acute need for more effective supply chain management in the healthcare sector. Moreover, in recent years, healthcare organizations have been under increasing pressure to improve profitability and tackle rising supply chain costs. In fact, it has been reported that hospitals could save around $12 million annually by improving hospital supply chain management.

By improving healthcare supply chain management, hospitals, healthcare providers, pharmaceutical companies, and other stakeholders in the healthcare sector can not only eliminate supply chain inefficiencies and cut unnecessary supply chain expenses but also build agility and resilience into the healthcare value chain. With a more agile and resilient healthcare supply chain, upstream and downstream partners will be able to better respond to sudden events like natural disasters or a global pandemic and work together more effectively to improve patient outcomes and save lives.

The main objectives of healthcare supply chain management are to increase visibility and efficiency across the supply chain and, in recent months, this has also come to include the strategic goal of improving supply chain agility and resilience—a must during these times of increased uncertainty and volatility in both supply and demand conditions. Getting health supply chain management right means that supply partners are better able to detect and resolve bottlenecks, potential disruptions, and other issues arising anywhere in the end-to-end supply chain. It can help improve patient care and safety while at the same time reining in waste and unnecessary spending.

The main activities involved in healthcare supply chain management include monitoring and supporting the flow of medicines, medical supplies and equipment, and medical services from manufacturer to patient. It includes supply chain quality management and planning, supply chain automation and optimization, and supplier relationship and risk management. When firms leverage digital tools and technology to carry out healthcare supply chain management, it involves using actionable insights obtained from multi-sourced data to continuously adjust and optimize supply chain systems and processes.

Supply Chain Integration and Strategic Partnering

In today's competitive markets, most companies have no choice; they are forced to integrate their supply chain and engage in strategic partnering. This pressure stems from both their customers and their supply chain partners. How can integration be achieved successfully? Clearly, information sharing and operational planning are the keys to a successfully integrated supply chain. There are important questions the supply chain manger should answer while integrating supply chain, including:

- ✓ What information should be shared?
- ✓ How should it be used?
- ✓ How does information affect the design and operation of the supply chain?

2.8 Developing pharmaceutical Supply Chain Maps

What is pharmaceutical supply chain mapping?

Mapping your supply chain means gathering information about your suppliers, their own suppliers, and the people who work in your supply chain, to create a global map of your supply network. To make analysis easier and more convenient, this information can be stored in a single platform. The supply chain mapping process isn't a one-time exercise; it's an ongoing process as your supplier and supply chain change.

Why is pharmaceutical supply chain mapping important?

The process of healthcare (pharmaceutical) supply chain mapping brings numerous benefits to a business that go far beyond simply providing visibility and meeting legal requirements. Some of the benefits include;

- ✓ It allows you to put strategies in place to rapidly react when there are supply chain problems like a supplier faces a shortage, an order gets lost in the system, there's a surge in demand or something even more unexpected happens.
- ✓ Comply with legislation
- ✓ Create supply chain transparency and visibility.
- ✓ You also develop a deeper understanding of the surrounding costs, timeframes, and risks, and thereby gain an advantage over competitors who lack this important knowledge.

2.9 How to develop pharmaceutical supply chain map

There are four key steps in the supply chain mapping process.

1. Learn where suppliers and their suppliers are located by working with procurement and using existing supplier lists.
2. Integrate information on your suppliers from different sources using a spreadsheet or data platform. Supply chains can change rapidly; a system for managing supplier data will help you to keep information current and in one place.
3. Conduct an initial risk assessment to help you prioritize where to focus next.
4. Use several tools to research your suppliers. Collect information about what is happening at supplier worksites, and research the inherent risks associated with the countries and sectors they operate within.

- **Note**: Continue this process as your supply chain grows – the more information you have, the more insight you'll gain. Once you have a good idea of your top tier sites, start looking at the sites that supply to them, i.e. their suppliers.

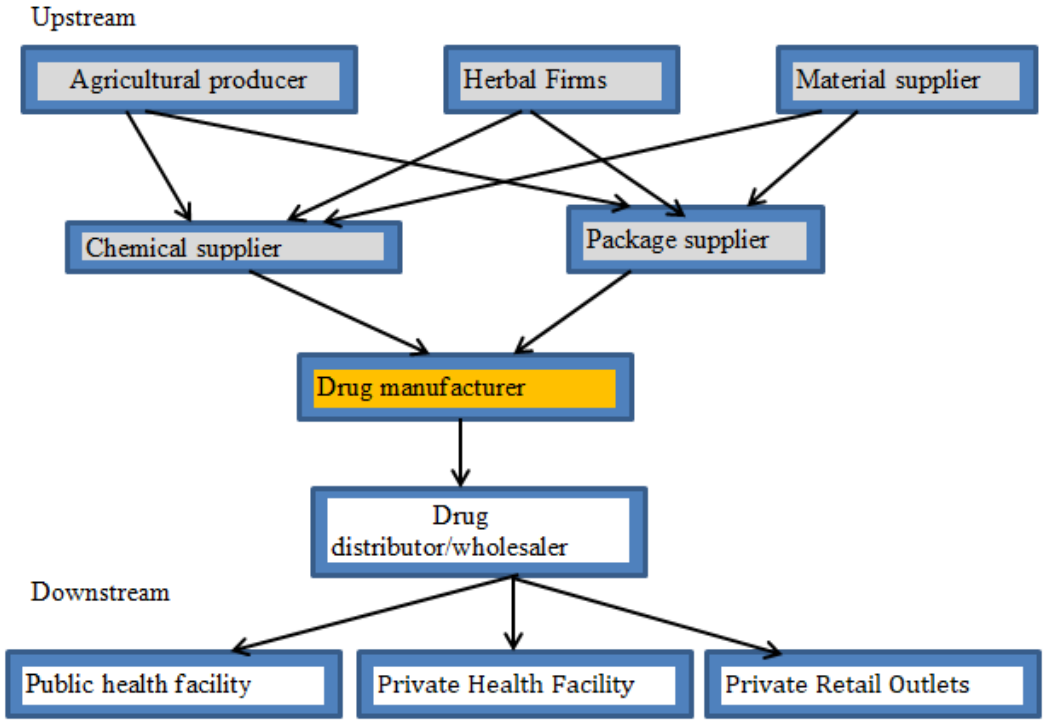


Figure 4: Example of a vertical supply chain map (*adopted and from Healthcare Supply Chain Management; Basic Concepts and Principles, and amended to Ethiopian context*)

2.10 Globalization and supply chains

Brainstorming

a. How do you see the growing impact of globalization on the pharmaceutical supply chain?

In recent decades the world has become much, much smaller than it used to be. The internet and significant improvements to transportation infrastructures has turned the world into one globalized international trade market.

This global market offers businesses opportunities to reach new customers and secure a diverse selection of new workers, materials, and products. Though the opportunities associated with globalization are numerous, the risks it poses to your supply chain may be bigger than you expect.

What is Globalization?

The term "globalization" refers to the free movement of goods, services, and people across the world. In regards to supply chain management, globalization refers to the process in which a business operates on an international scale.

Globalization trade offers companies the opportunity to reach new customers in new markets, which dramatically upsets how manufacturers need to operate to be successful. Exposure to new markets means exposure to greater competition and greater risk; but also greater reward.

Pros and Cons of Global Supply Chain

Logistics manager or business owner may be wondering whether the impacts globalization has on supply chain will be beneficial or simply make it harder for them to operate. The truth is that there are pros and cons to globalization and it may, or may significantly affect supply chain. It all depends on the nature of your business and how you manage your supply chain.

Benefits of a Globalized Supply Chain

The onset of globalization means supply chain management is more complex and business critical than ever before. As supply chain managers or business owners, logistics optimization falls on you, and it is your responsibility to know how globalization can benefit your operation. Reach new customers in new markets around the world – Globalization simplifies

communication between business owners, vendors, and customers and therefore makes it easier to reach new markets and stay connected with customers no matter where they are in the globe.

Expand sourcing opportunities: Globalization makes it possible for businesses to increase production by securing a diverse selection of workers, raw material, and products from regions of the world that were previously out of reach. This can result in significant labor costs.

Offer a larger selection of goods and services: Global sourcing opportunities mean an increase in the range of products and services that you can provide for your customer.

Grow and expand the scope of their business: Globalization makes communication near effortless, which make it easier for markets to expand and diversify, thus providing more opportunities for businesses owners to capitalize. Save money and increase profits: more options to source from and to capitalize on means more chances to save on spending and a greater chance of profit.

Negatives of a Globalized Supply Chain

The benefits of a globalized supply chain are numerous but it also presents a new set of challenges to supply network and managing your supply chain. To take advantage of the benefits of globalization, you need to know the negatives and how to respond to them.

Greater complexity: Global supply chains have global problems. As companies globalize they must scale up all aspects of their business, especially their supply chain.

Increased supply chain risk: When your materials, factories, and customers are spread around the globe that means your business is entirely at the mercy of global events, like natural disasters, port and border closures and changes to the geo-political landscape, or more recently, an event like the COVID-19 pandemic. Another example is when factories in China close for several weeks for the Chinese New Year, which can result in supply chain disruption.

Increased competition: You can bet that if your company broke into a new market that there are several companies just like yours with the have access to the exact same supplies, products, manufacturing, and customers as you. The global economy requires supply chains to be as lean and efficient as possible.

Greater data collection challenges: When different aspects of your supply chain are scattered around the globe, the process of data collection and oversight grows in complexity and becomes more difficult.

More legal issues: Operating across borders means operating in countries with different legal systems, which can get complicated and expensive very quickly.

How Globalization is Affecting Supply Chain?

Globalization is, for better or worse, a good thing for your supply chain, your business and the world at large. It's true, globalization poses substantial risk to your business but only if you do not take steps to insulate your supply chain from the worst of its effects. Because the benefits that globalization will bring to your business far outweigh the risk.

CHAPTER 3: SELECTION OF PHARMACEUTICALS

Chapter description:

This chapter will introduce essential medicine concept and the selection process of pharmaceuticals at any level of the health care system or for any program. It covers criteria to consider, steps to follow and source of information used during selection of pharmaceuticals.

Chapter objectives:

At the end of this chapter students will be able to:

- Describe essential medicine concept and its principles
- Describe pharmaceutical selection and its rationale
- Identify criteria used in selection of pharmaceuticals
- Differentiate pharmaceutical list, formulary manual and standard treatment guideline
- Explain formulary process and steps in pharmaceutical selection
- Differentiate types of names for pharmaceuticals
- Identify sources of information used during selection of pharmaceuticals
- Conduct pharmaceutical selection

3.1. Essential Medicine's Concept

3.1.1. Historical background

- During and soon after WWII, a number of pharmaceuticals were introduced to the pharmaceutical market and the whole field of therapeutics was revolutionized.
- 'Miracle' was the word used by many authors to describe the effects.

- From the global perspective, however, such miracles were for the minority (for affluent countries)
    - **In many countries, there was increasing gap in access to drugs:**
        - Two problems existed side by side: no drugs at all in the countryside, but 100s or 1000s of drugs competing for customers' attention in the cities.
    - **The pharmaceutical market also produced a series of disasters:**
        - Inadequately tested or misused drugs resulted in many cases of serious or fatal drug-induced diseases before sufficient evidence accumulated in the public eye to mandate change.
    - **So there was a growing recognition that pharmaceuticals often brought problems as well as great promise.**
- Some of the complaints in the early nineteen seventies were:
    - No links between drugs and health needs
    - No access to most needed drugs
    - Rising costs of pharmaceuticals
    - Uneven rural-urban distribution
    - Protests against industry marketing practice
- Against this background ⇒ birth of the essential drug concept (i.e. why not concentrate first on a basic list of reliable drugs to meet the most vital needs)
- The idea was based on past positive experiences:
    - Doctors & travelers carried limited drugs and satisfied basic need of the community where they go.
    - The basic list idea, whereby a limited range of affordable drugs used to meet basic needs of whole populations, had been in place for the first time before the WWII, in Norway and was successful.
    - Later on Papua New Guinea (early 1950's), Sri Lanka (1959), and Cuba (1963) followed.
- WHO adopted the concept with the view that any safe and efficacious medicines should be allowed for sale, but that essential medicines should be given priority.
    - WHO defined **essential medicines as those that satisfy the priority health care needs of the population** in 1975.

- In 1977, WHO published the first model list of essential drugs which was considered as a major breakthrough in the history of medicine, pharmacy and public health.
    - The first list contains around 200 active substances.
        - Served as a guide for the development of national and institutional essential medicine lists
        - Led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity.
    - List is revised every 2-3 years by WHO expert committee.
    - The 2011 revision contains around 350 active substances.
- In 1978, historic goal of 'health for all by 2000' was introduced at an international conference on primary health care in Alma Ata and essential medicines were recognized as one of the eight elements of primary health care.
- Different countries prepared their own essential medicine list by adopting WHO model list of essential medicines

3.1.2. Essential medicine concept and its principles

The recent definition of essential medicines, according to WHO is **those that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts in appropriate dosage forms and at a price the individual and the community can afford.**

The concept of essential medicines: A limited range of carefully selected medicines leads to better health care, better management and lower costs.

- It embraces the following guiding principles:
    - The vast majority of health problems for most members of the population can be treated with a small, carefully selected number of drugs.
    - In practice, most doctors and other health professionals routinely use fewer than 200 drugs. Training and clinical experience should focus on the proper use of these few drugs.
    - Procurement, distribution and other supply activities can be carried out most economically efficiently for a limited number of pharmaceutical products.

- Patients can be better informed about the effective use of drugs when the number of drugs they are confronted with is limited.

Selection criteria: Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness

Purpose: Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

Implementation: The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.

3.2. National essential medicine list

A national Essential Medicine List (EML) describes the medicines that satisfy the priority health care needs of a population, and are approved for use throughout the country. As described earlier, WHO publishes a model list of essential medicines that individual countries can adapt and use to develop their own national EML. It is countries responsibility to consider the local context and disease patterns when preparing EML. National EML is used as a base to prepare facility specific medicine list. Preparation of a national EML involves two processes:

1. **Registration of pharmaceutical products**

In most countries, pharmaceutical products require prior evaluation and approval from a regulatory body, often called the national drug regulatory authority. Products should be proven to be effective, safe, and of good quality before they are registered. Some countries also consider the cost of the product, or whether it is needed. Because the quality of the medications is checked as part of the registration process, each brand (produced by different manufacturers and locations) is registered independently. In most cases, not only the product, but also the packaging, and labeling and use information is registered.

Many pharmaceutical products registered for use in a country may not be on the national EML, or on the standard treatment guidelines. Products are registered if their efficacy, safety, and quality are acceptable to the regulatory authority. While they may not be on the EML, they may

be used by the private sector and, in some cases, even used by public sector practitioners on rare occasions.

Failure to follow the pharmaceutical registration protocol could lead to products being held up by customs when they enter the country. Not only does this delay the delivery of important health care products, but it wastes time, costs money, and risks spoilage or expiry of products while at customs.

2. Selection of essential medicines

A committee composed of various disciplines including physicians from different specialty, pharmacists, nurses, laboratory technologists, ministry officials should be organized. Evidenced based approach should be applied to determine medicines that will be included on the national EML. Often a product should be relevant to the local disease patterns; proven to be of good quality, effective, and safe; cost-effective when considering total treatment cost.

Often, as part of the development of the national EMLs, countries define at which levels of care in the health system each product will be used, based on disease patterns and complications commonly treated at each level. For example, not all disease conditions are treated at every facility in the country. Second-line antiretroviral treatment may not be provided in the rural health center, but may be available at the district hospitals and higher levels.

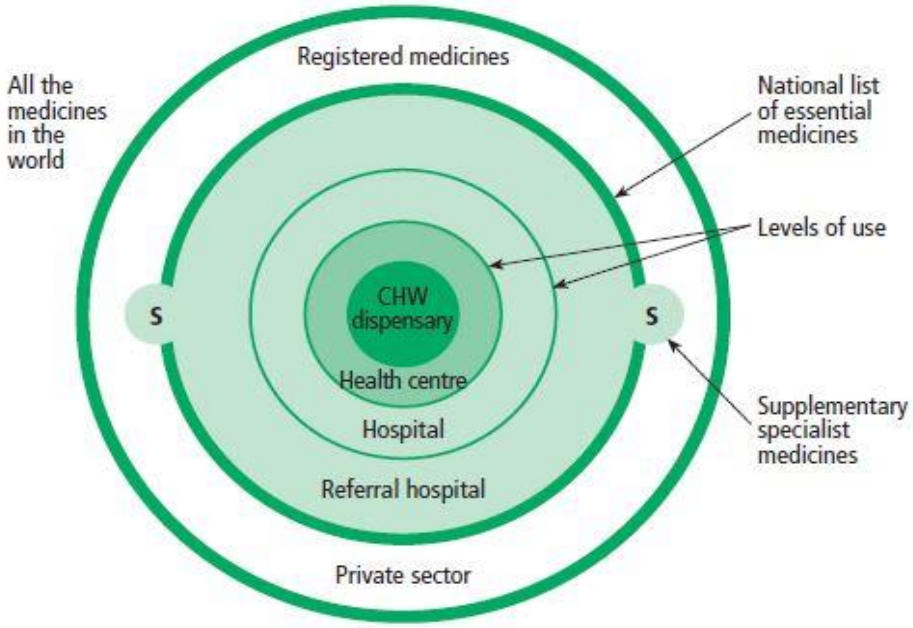


Figure 3.1: The essential medicines target: the national or institutional list of essential medicines is a subset of registered medicines, divided by level of care

Source: WHO policy perspectives on medicines-The selection of essential medicines. 2002.

Note:

- ✓ The essential medicines list aims to identify cost-effective medicines for priority conditions with special emphasis on public health aspects and considerations of value of money.
- ✓ The list of essential medicines relate closely to guidelines for clinical health care practice, which are used for the training and supervision of health professionals.
- ✓ It guides the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production.
- ✓ Core list presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions.
- ✓ Complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt, medicines may also be listed as

complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings.

3.3. Pharmaceutical selection and its rational

What is pharmaceutical selection?

Pharmaceutical selection is a process of deciding the type of needed pharmaceutical products for health service at any level of the health care system. It is the process of identifying and picking out a number of essential pharmaceuticals in order to achieve better supply, more rational use, and lower costs. It emanates from the essential medicine concept.

As much as 70% of the pharmaceuticals on the world market are duplicative or non-essential. Many are minor variations of a prototype drug and offer no therapeutic advantage over other drugs that are already available**.** Other drugs show high toxicity relative to their therapeutic benefit**.** Some drugs are newly released with insufficient information on their efficacy or toxicity**.** Many new products are for therapeutic indications not relevant to the basic needs of the population, which are more expensive than existing drugs**.**

With so many drugs available, it has become impossible for prescribers to update and compare alternatives**.** Variety of available products may also contribute to inconsistent prescribing within the same health care system or health facility**.** With regard to procurement, purchasing power is significantly lessened by the large number of duplicate and non-essential drug products.

In short, pharmaceuticals can provide great benefits, but their cost is substantial. For one thing, no country or program can afford to purchase all pharmaceuticals circulating in the market within its given budget. For the other thing, the limited funding available shouldn't be spent on ineffective, unnecessary or even dangerous medications. Careful selection of pharmaceuticals has considerable impact on quality of care (clinical implications) and cost of treatment (cost implications), and it is therefore one of the areas where intervention is most cost-effective.

Generally the rationale for selecting a limited number of essential pharmaceuticals is that it may lead to:

1. **A better supply**
    - ✓ Easier procurement, storage and distribution
    - ✓ Adequate stocks
    - ✓ Better quality assurance
    - ✓ Easier dispensing
2. **More rational prescribing and dispensing**
    - ✓ More focused training and drug information
    - ✓ More experience with fewer pharmaceuticals
    - ✓ No irrational alternatives available
    - ✓ Better recognition of drug related problems
3. **Lower cost**
    - ✓ Increased competition, lower cost
4. **More rational patient use**
    - ✓ Focused patient education
    - ✓ Reduced confusion and increased adherence to treatment

3.4. Criteria for Pharmaceutical selection

Although, there are many different settings in which selection of pharmaceuticals is done, the criteria for selection is almost similar. The most commonly used criteria are:

1. Relevance to the pattern of prevalent diseases
2. Availability of facilities (diagnostic facilities, treatment facilities, physical facilities for storage and distribution and other facilities)
3. Training and experience of available personnel
4. Pharmaceutical products only for which sound and adequate scientific data on efficacy, safety, quality, bioavailability and stability are available
5. Possibilities of easy and prompt procurement and local manufacture
6. Pharmaceutical products with widest possible coverage for the prevailing diseases

7. Pharmaceuticals with affordable cost by considering total cost of treatment not only the unit cost of drug(s)
8. Priority to single ingredient pharmaceutical products instead of fixed ratio combination products unless the advantage outweighs. Selection of combination of drug products is acceptable only if the following advantages are met:

- ✓ Clinical documentation justifies the combination/concomitant use of more than one drugs
- ✓ The therapeutic effect is greater than the sum of effect of each
- ✓ The cost of combination product is less than the sum of individual products
- ✓ Compliance is improved
- ✓ Sufficient drug ratios are provided to allow dosage adjustments satisfactory for the majority of the population.

When two or more pharmaceuticals seem similar in the above respects, select:

- The most thoroughly investigated pharmaceutical
- Pharmaceutical(s) which offers better patient compliance
- Pharmaceutical(s) which are locally available

3.5. Formulary process and steps in pharmaceutical selection

3.5.1. Formulary process

Key Definitions:

1. **Formulary process**: is an overall set of activities and procedures to develop pharmaceutical list, formulary manual and standard treatment guideline
2. **Pharmaceutical list**: is a list of pharmaceutical products approved to be used in a specific health care setting
3. **Formulary/Formulary manual**: is a drug-focused document that contains summarized information on selected drugs. It acts as a precise source of drug information in addition to the benefits similar to a drug list

4. **Standard treatment guideline (STG)**: A systematically developed, disease-focused document designed to assist practitioners in making decisions about appropriate health care for specific clinical circumstances

The common approach to develop pharmaceutical list, formulary manual and STG is to start with a list of health problems to be managed at a given level of health care and identify choice of treatment for each problem. Preparing pharmaceutical list is nonsense if it is not paralleled with developing drug formulary and standard treatment guideline. They are interdependent and should be developed in a systematic way. The preferred process is to prepare STG first, then compile pharmaceutical list and develop summary information for the pharmaceuticals (formulary manual); or otherwise accomplish all in parallel. This approach ensures that the supply of pharmaceuticals which is based on the national/local list of pharmaceuticals is consistent with the treatment guidelines in public sector facilities and that summary drug information is available for all medicines supplied in the public sector.

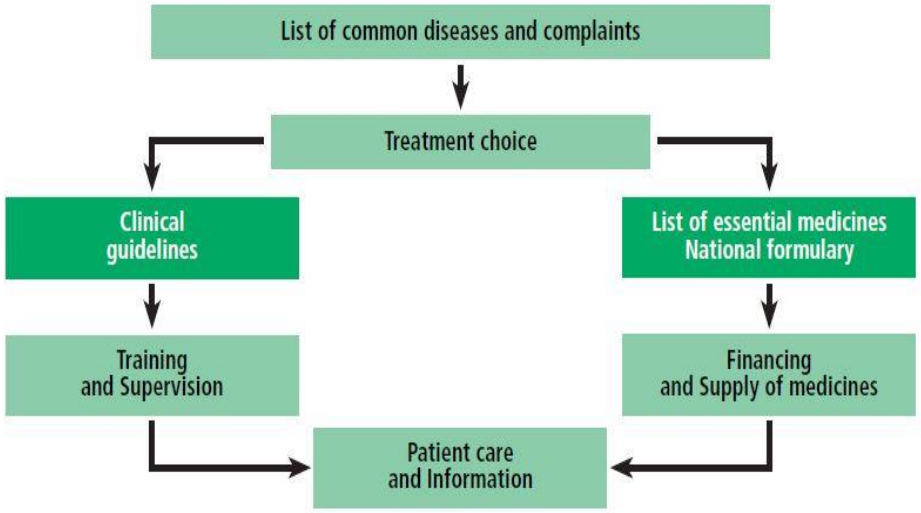

List of common diseases and complaints
Treatment choice
Clinical guidelines
List of essential medicines National formulary
Training and Supervision
Financing and Supply of medicines
Patient care and Information

Figure 3.2: The list of common health problems guides the formulation of clinical guidelines, the list of essential medicines, training, financing and supply-leading to improved patient care (Source: WHO policy perspectives on medicines-The selection of essential medicines. 2002.)

Students' Activity # 1

Activity type: Group assignment (students will be grouped each having 5 members)

Activity topic: Review of pharmaceutical list, STG and formulary manual

Activity detail: You will be provided with national drug list, hospital pharmaceutical list (if any), national STG and national formulary documents. Review the documents and outline the difference in the type of information included. Each group will present their findings in the next session for which 10 minutes is allotted.

3.5.2. Steps in pharmaceutical selection

Pharmaceutical selection involves the following basic steps whatever the level of preparation:

1. **Establish pharmaceutical selection committee**

Pharmaceuticals should be selected by a committee, composed of prescribers, pharmacy personnel and other concerned health personnel. Including a pharmaceutical supply chain manager on this committee adds a needed perspective on how their selections could impact the supply chain and, eventually, product availability. Often the need to make informed choices and tradeoffs arise in the selection process. For example, product characteristics, such as packaging and cold chain requirements, have significant supply chain implications. If the most ideal product requires cold chain, and most facilities do not have a reliable cold chain, then an alternative product may be included on the list.

2. **Determine the prevalent health problems and patient characteristics**

Prominent health problems in a given area can be determined by referring different data sources including morbidity registration book, surveys and other relevant materials. The morbidity data should be complete and reliable. The recorded data should be summarized and analyzed by age, sex, severity, frequency and ranked using percentage.

3. **Decide which health problems may be treated at the level of pharmaceutical selection**

The range of health problems which can be treated at a given facility can be identified by considering factors such as

- The level of training of health personnel involved in prescribing
- Available diagnostic facilities such as x-ray, ultrasound etc.
- Level of services provided i.e. curative, preventive, and other services like initial treatment, complete treatment, follow up treatment.

Details of patient characteristics (age, sex…) and nature and severity of the health problems to be managed also should also be outlined as pharmaceuticals needed may depend on such factors.

4. Choose the pharmaceuticals to be used for the health problems

Once the health problems are exhausted, selecting pharmaceuticals for each health problems is done by considering criteria outlined in the previous section.

5. Structure the list

The list of pharmaceuticals could be categorized by one or more of the following mechanisms

- Pharmacotherapeutic +alphabetic
- Level of health care (primary, secondary, tertiary; or health post, health center, primary hospital, referral hospital, specialized hospital….
- Level of importance or health impact (Vital-V, Essential- and Normal-use (less-essential)-N

VEN is an approach in which pharmaceuticalss are divided according to their health impact in to vital, essential and non-essential/normal-use categories.

- V: Vital drugs- potentially lifesaving, have significant withdrawal effect (making supply mandatory), or are crucial to providing basic health services. E.g. antimalarial drug, glove, syringe, anesthetic drug
- E: Essential drugs- effective against less severe but nevertheless significant forms of illness, but not absolutely vital to providing basic health services. E.g some antibiotics
- N: Nonessential drugs- used for minor or self-limiting illnesses. E.g. cough syrup, antacid

6. Introducing the list of pharmaceuticals to health professionals of the institution and other concerned bodies and finalize the list

The draft pharmaceutical list should be presented to health professionals from different department and comments should be incorporated before a final draft is dispatched.

7. **Updating the list of pharmaceuticals**

The list should be reviewed periodically. Any addition into and deletion should be on the basis of the selection criteria

The above points summarize the step-wise approach to develop pharmaceutical list. Additionally the following guidelines or issues should be considered during preparation of a pharmaceutical list:

- Pharmaceutical list should be prepared based on International Non-Proprietary (INNP) or generic name of products.
- A pharmaceutical list should include standardized description and specification. For example a medicine in the list must compose generic name, dosage form and strength. This is more difficult in the case of medical laboratory reagents, medical supplies and medical devices in which case consultation with professionals and referring specific standards of specification may be needed to outline minimum information for each products.
- Minimize the number of strengths stocked for the same medication; multiples of lower strengths can be used for infrequently needed higher strengths.
- Include second-line alternatives to medicines of choice as needed, but minimize therapeutic duplication.
- Ensure that pharmaceutical list at the facility level is in line with national list.

3.6. Pharmaceutical nomenclature

Pharmaceuticals usually medicines have three common names: chemical name, International Non-Proprietary (INNP) or generic name and proprietary or brand name

1. **Chemical name**
    - It is given when a new chemical entity is developed.
    - It is a scientific name based on the compound's chemical structure.
    - Often, the name is long and difficult to pronounce, and, since it has numbers,
    - It is almost never used to identify the drug in a clinical or marketing situation.

Example: 6-{D(-)-,a-amino-a-phenylacetamido}-penicillinic acid

2. **International Non-Proprietary (INNP) or generic name**

- The INN is the medicine's official name, regardless of what company or organization manufactures or markets it.
- They are assigned through WHO, following a well-established procedure.
- INN identifies a pharmaceutical substance or active pharmaceutical ingredient by a unique name that is globally recognized and is public property.
- As unique name, INN has to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use.
- Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common "stem". Example: all B-adrenoreceptor antagonists are given the suffix -olol.
- INNs are intended for use in pharmacopoeias, labeling, product information, advertising and other promotional material, pharmaceutical regulation, and as a basis for generic product names.
- The use of generic names for pharmaceutical purchasing as well as prescribing carries considerations of clarity, price, and quality.

Example: Ampicillin, Hydrochlorothiazide, Diazepam…..

3. **proprietary or brand name**
    - It is also called commercial or trade name
    - It is chosen by the manufacturer to facilitate recognition and association of the product with a particular firm for marketing purposes.
    - For most common medicines, there are several branded products that all contain the same active ingredient and therefore share the same INN.

Example: Augumentin®, Coartem®, Daonil®

Students' Activity # 2

Activity type: Group assignment (students will be grouped each having 5 members)

Activity topic: Identification of pharmaceuticals nomenclature

Activity detail: Visit a nearby pharmacy, identify 10 products and list the three types of nomenclature for each product. Each group will present their findings in the next session for which 5 minutes is allotted. Prepare your using the following template.

Ser No.	Generic name	Brand name	Chemical name
1			
2			
3			

3.7. Source of information for pharmaceutical selection

Searching for clinically relevant, up-to-date, user-specific, and unbiased drug information is essential for selection of appropriate drugs. The sources can be:

Primary Sources -are those which produce new drug information mainly as a research articles in journals. Example:

- Ethiopian Pharmaceutical Journal
- American Journal of Health System Pharmacy
- British Journal of Clinical Pharmacology
- British Medical Journal

- Lancet, etc…

Secondary Sources-are those which provide reviews of the research articles that appear in primary sources. Abstracting systems are also considered as secondary sources. Note that primary sources may have review articles in addition to research articles. Example:

- Drug and therapeutic bulletin
- Adverse drug reaction bulletin
- Pharma forum, by Ethiopian Pharmaceutical Association

Tertiary Sources/general sources-Present documented information in a condensed format**. These include** standard reference books which range from simple medical dictionaries to more specialized texts. Example:

- National drug formularies
- Martindale – the extra pharmacopoeia
- Standard treatment guidelines
- Different pharmacology, pharmacotherapy and other books

Students' Activity # 3

Activity type: Exercise

Activity topic: Pharmaceutical selection practice

Activity detail: you are provided with an exercise here below to practice pharmaceutical selection. Answer the given questions (show necessary steps).

Exercise 1:

Assume you are deployed as pharmaceutical supply personnel in a new district hospital. The following health problems are identified as priority diseases in the area:

- Pneumonia (community acquired)
- Typhoid fever
- Bacillary dysentery
- Malaria
- Amoebiasis

Based on the above health problems:

1. Select required medicines (hint: consider patient characteristics and severity of diseases and 1st line and alternative treatments for selecting medicines). Show the necessary steps.
2. What criteria did you use to select pharmaceuticals?
3. What are the sources of information you used?

Chapter Summary:

- Essential medicines concept entails the issue of having limited range of carefully selected medicines which leads to better health care, better management and lower costs.
- The practice of developing national essential medicine list and pharmaceutical selection for different levels of the health care system emanates from essential medicine concept.
- Pharmaceutical selection, a process of deciding the type of needed pharmaceutical products for health service at any level of the health care system, should be done by using sound criteria and by following rational approaches and guidelines
- Source of information matters in evidence-based pharmaceutical selection

References and further reading

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CHAPTER 4: PHARMACEUTICAL QUANTIFICATION

Chapter description

This chapter addresses concepts and importance of pharmaceutical quantification. It also introduces key phases as well as methods of quantification. The rational approaches for reconciliation of pharmaceutical cost with budget are another issue to be entertained.

Course objectives

At the end of this chapter the students will be able:

- ✓ Define key terminologies in pharmaceutical quantification
- ✓ Explain the importance of pharmaceutical quantification in supply chain management
- ✓ Identify the key steps or phases in pharmaceutical quantification
- ✓ State activities for initiating, reviewing and updating quantification
- ✓ Compare and contrast the different methods of quantification
- ✓ Conduct pharmaceutical quantification using different methods
- ✓ Reconcile pharmaceutical demand with budget

4.1. Introduction

Pharmaceutical quantification is the process of determining the amount of pharmaceutical products needed for the purpose of procurement. It involves estimating not only the quantities needed of a specific item but also the financial means required for purchasing the item. Quantification is important to ensure that adequate amount of appropriate drugs are available to treat the expected case load within a country/region/zone/health facility. Appropriate drug quantification can avoid shortage of (out of stock) as well as overstock of drugs.

Quantification includes forecasting and supply planning. Forecasting is the process of estimating the quantities of products that will actually be dispensed or used to meet the health needs of the targeted population during a specific future period of time. Forecasting can be based on historical consumption (quantities dispensed or used), services, morbidity and/or demographic data, and assumptions about future demand, program plans, and performance. When historical data are unavailable or unreliable, assumptions will also be needed to estimate program performance and product consumption. Supply planning involves determining the total product quantities and

costs required to fill the supply pipeline to ensure optimal procurement and delivery schedules, taking into account forecasted consumption, minimum and maximum stock levels, order and shipping lead times, and desired arrival dates of shipments.

Indicators of poor quantification:

- Shortage of drugs
- Overstocking of drugs
- Irrational prescribing
- Inefficient budget use
- Suppression or distortion of demand

4.2. Importance of quantification in supply chain management

Quantification, a critical supply chain management activity, links information on services and pharmaceuticals from the facility level with program policies and plans at the national level to estimate the quantities and costs of the pharmaceuticals required for a health program.

Quantification is important for informing supply chain decisions on product selection, financing, procurement, and delivery. The results of a quantification exercise help program manager to:

- ✓ Identify the funding needs and gaps for procurement of the required commodities
- ✓ leverage the sources, amounts, and timing of funding commitments to maximize the use of available resources
- ✓ Advocate for additional resources, when needed
- ✓ Develop a supply plan to coordinate procurements and shipment delivery schedules to ensure a continuous supply of pharmaceuticals.

4.3. Key steps in quantification

No matter which pharmaceuticals a program distributes, a quantification exercise follows three key steps: **preparation, forecasting, and supply planning**

Preparation phase: involves assembling quantification team, describing the program/setting for quantification, defining the purpose and scope of the quantification exercise (products, timing, etc.) and Collecting required data (for forecasting and supply planning).

Forecasting phase: this phase involves using the data collected during the preparation step to estimate the quantity of each product that will be dispensed or used during each year of the quantification. These quantities are the basis for calculating the total commodity requirements in the supply planning step. Forecasts can be prepared based on historical consumption (quantities dispensed or used), services, morbidity and/or demographic data, and assumptions about future demand, program plans, and performance.

The forecasting step in a quantification exercise is a four-part process:

- Organize, analyze, and adjust data (demographic, morbidity, service, consumption)
- Build and obtain consensus on the forecasting assumptions
- Calculate the forecasted consumption for each product
- Compare and reconcile results of different forecasts

Supply planning phase: This step is used to estimate the total commodity requirements and costs for a program or facility. To calculate this estimate, start with the forecasted consumption for each product from the forecasting step; then, consider the existing stock on hand; any quantities of product already on order, but not yet received; and the established maximum and minimum stock levels. Be sure to include procurement and supplier lead times and provide a buffer stock for unexpected delays.

The supply planning process includes

- Organize and analyze data (data for the supply planning step are different from the data for the forecasting step but can be collected at the same time.)
- Build supply planning assumptions.
- Estimate total commodity requirements
    - First additional quantities of product needed to cover procurement and supplier lead times, and to maintain stock levels between the minimum and maximum
    - Stock on hand, stock on order should be subtracted and quantity of products that will expire before use should be added
    - Costs per procurement unit plus freight, customs, and other shipping fees will give total cost
- Develop supply plan (shipping quantities and delivery schedules)
- Compare costs to available funding.

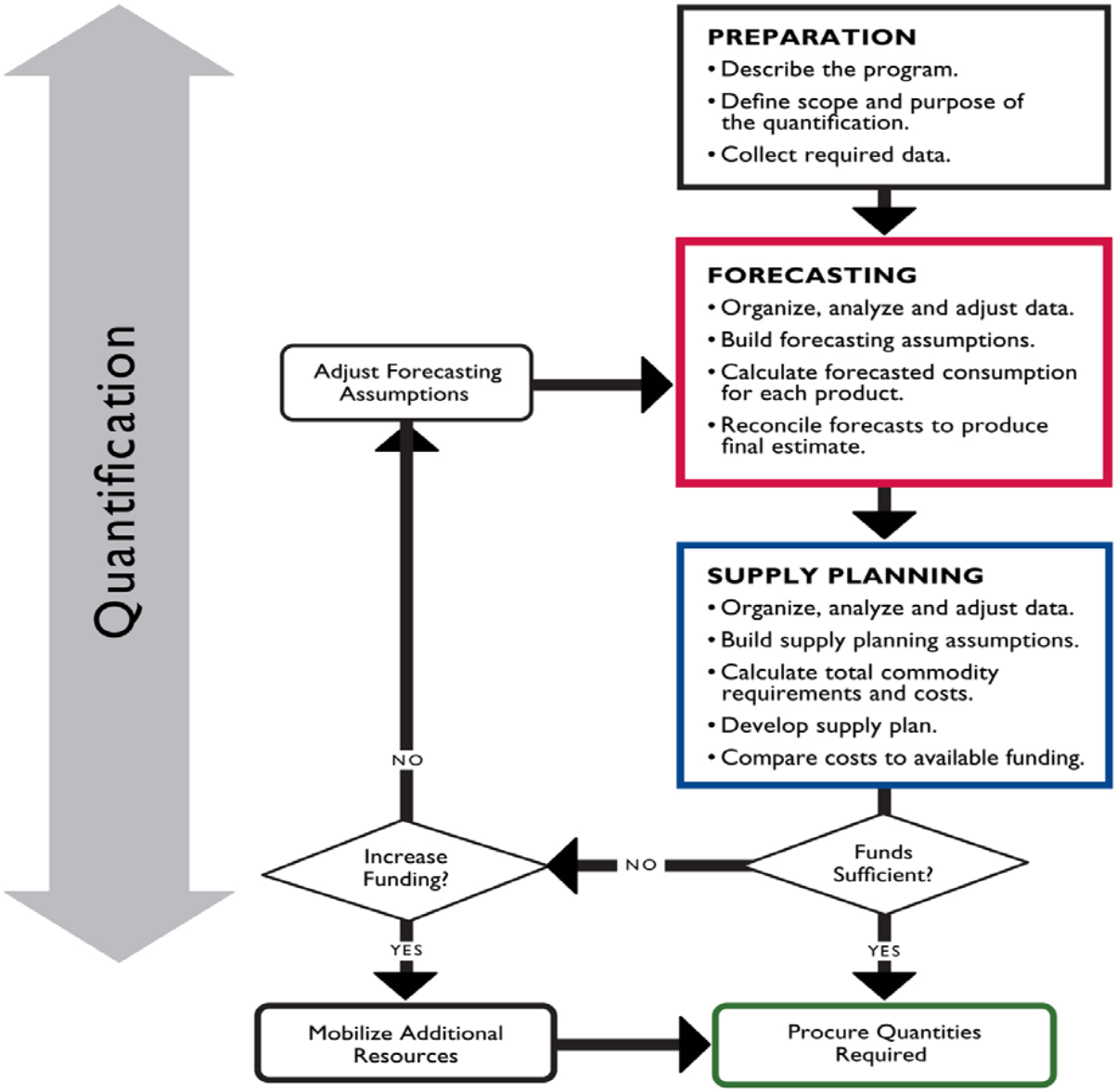

Figure 4.1: steps in quantification (Source: USAID | DELIVER PROJECT, Task Order 1. The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities, 2011)

4.4. Process for initiating, reviewing and updating quantification

- Quantification does not end after you determine the final product quantities and costs; it is an ongoing process of monitoring, reviewing, and updating the forecasting data and assumptions; and recalculating the total pharmaceuticals requirements and costs, as needed.

- ❖ For the quantification exercise to be useful and effective, you should review the forecasting assumptions and the supply plan at least every six months; and more frequently for rapidly growing or changing programs.
- ❖ Ideally, the same core team of people who conducted the initial quantification should conduct routine updates.
- ❖ Many country programs have instituted a quarterly quantification review process for specific pharmaceuticals categories.
- ❖ Ongoing monitoring and updating of the quantification is critical to keep program managers, donors, and other stakeholders informed on the availability of drugs; is required for timely decision making about product selection, financing, and delivery of pharmaceuticals.

Reviewing and updating the quantification includes the following activities:

- ✓ Reviewing and updating the forecasting data and assumptions
- ✓ calculating or recalculating the forecasted consumption (using quantimed, excel spreadsheets, or other software)
- ✓ Updating the stock on hand for each product
- ✓ assessing national stock status for each product (based on product consumption and stock levels)
- ✓ Reviewing and updating shipment delivery schedules to ensure continuous supply and maintain desired stock levels.

4.5. Methods of pharmaceutical quantification

There are four basic methods for estimating pharmaceutical quantities:

1. Morbidity method (patient morbidity standard treatment method)
2. Consumption method
3. Adjusted consumption method (proxy consumption method)
4. Service-level projection of budget requirements

1. Morbidity method

Morbidity method estimates the need for specific medicines based on the expected number of attendances, the incidence of common diseases, and standard treatment patterns for the diseases considered. The key assumption in this method is service providers will adhere to established treatment guidelines.

Morbidity method is more appropriate under the following conditions:

- ❖ Available consumption data are incomplete or unreliable
- ❖ Prescribing patterns are not cost effective
- ❖ The budget is unlikely to be sufficient to meet estimated requirements
- ❖ The heath facility or services concerned are not expanding or contracting rapidly

Advantages:

- ➢ Does not require drug consumption data
- ➢ Provides a systematic basis for reviewing drug use and prescribing
- ➢ Motivate reliable morbidity recording
- ➢ More realistic and provide more reliable estimated picture than the two methods

Disadvantage:

- ➢ It requires detailed morbidity data and agreed standard treatment schedule which are usually unlikely to obtain
- ➢ It requires an essential drugs list that includes therapy for the problems
- ➢ Requires more detailed calculations
- ➢ Supply will not match use if standard treatments are observed

Basic steps in morbidity method of quantification

Step-1: Specify the list of health problems

Depending on the level of health facility or program, for which quantification is to be done, the range of health problems that can managed should be identified

Step-2: Prepare average standard treatment schedules for each health problems

- ❖ Average standard treatment schedule is the average quantity of a drug per course of treatment. Average treatment schedule are valid if they represent the average treatment

which shall actually be used clinically. Average standard treatment schedule to be used should include the following;

- The name of health problem and code No. of the diagnosis (ICD). It should also include severity of the disease.
- The patients age (age category), sex
- The generic name, strength, dosage form of each drug to be used for the treatment.
- The average dose, number of doses/day, number of days these doses are to be given (duration).
- The total average quantity of each dug used for a standard course of treatment.

Quantity of drug needed for a given case is calculated using the following formula:

$Q_E = D_{CU} \times N_D \times L_D$

Q_E= Quantity needed for each treatment episode in each standard treatment regimen

D_{CU}= Basic Unit per Dose

N_D= Number of Doses per Day

D_T= Duration of Treatment

Example: the following table shows average treatment schedule for Amoebiasis. Determine the average quantity of metronidazole 250mg capsule needed for an adult case.

Diagnosis		**Generic name, strength and dosage Form**	**Dose (D_{CU})**	**No. of doses/day (N_D)**	**No. of days/ duration (D_T)**	**Amount/ course of treatment (Q_E)**
Amoebiasis	**Adult**	Metronidazole 250mg	3	3	5	45
	Child	Metronidazole 250mg	1	2	3	6
		Metronidazole 125mg/5ml susp.	10ml	2	3	60ml (1 bottle)

Solution:

$Q_E = D_{CU} \times N_D \times D_T$

The quantity of metronidazole 250mg capsule needed to treat Amoebiasis for a single adult patient is

QE= 3 x 3 doses per day x 5 days = 45 capsules

Step-3: Select the review period to review morbidity data

The duration of time to quantify drug requirement and hence the length of time to take morbidity record should be specified. If it an annual quantification, a one year morbidity record will be reviewed.

Step-4: Estimate number of treatment episodes for each health problem

- A treatment episode is a patient contact for which standard course of drug treatment is required.
- The quality and reliability of the morbidity data is very important. If the morbidity data are seriously incomplete then the drug estimate may be dangerously inadequate or inappropriate.
- The number of treatment episode can be estimated as follows;
    - ❖ Reorganize the diagnosis according to the health problems defined in the average standard treatments.
    - ❖ Within health problems break down the number of patient contact as necessary by age, sex, and severity if treatment varies with these variables
    - ❖ Determine the proportion of contacts for which the standard treatment is required.

$E_T = N_C$ X F

E_T = Number of treatment episodes

N_C= Expected total number of contacts in thousands

F= The frequency of health problem estimated per 1000 contacts

There were 3,123,408 contacts and there were 364 episodes of Amoebiasis per 1,000 patients, therefore:

E_T= 3,123,408 x 364/1000= 1,136,921

Step-5: calculate the total quantity of each drug(s) required

a) Calculate the total quantity for each drug for each health problem

Total quantity of each drug for each health problem =	No. of treatment episodes for the health problem	X	Quantity of each drug specified for a standard course of treatment

Example: If the number of treatment episode for Amoebiasis treated annually by a given health center was 1000, of which 60% were adults and all cases were treated with metronidazole 250mg capsule the quantity of metronidazole can be calculated as follows:

- Quantity of drug per course of treatment = 45 capsules
- Number of treatment episodes = 1000 x 0.6 = 600

So quantity of metronidazole 250mg capsule required for Amoebiasis in the health center = 45 capsules * 600 cases

b) Combine the estimates for each drug for various health problems into a master procurement list

When a drug is indicated for more than one health problems, add the quantities required for each one to obtain the total quantity of each drug by reorganizing the quantities in step5a by the drug to be quantified.

Step-6: Adjust quantities for different reason (wastages/losses, service expansion, stock on order, stock on hand….if needed)

Example: If the number of patients getting service in your health institution increases by 10% every year add to the amount calculated 10% for service increment.

Step-7: convert quantities in to order pack size

No. of order packs = Total quantities required/pack size

Step 8: estimate total pharmaceutical cost

- First enter estimated unit cost for each pharmaceutical. When estimating the cost of medicines on a quantified list, the critical issue is determining the next purchase prices. Using the last purchase prices is not adequate, because in most cases, doing so results in an underestimate of the actual next purchase prices, leading to insufficient funds when

the time comes to place orders. Two basic ways exist to estimate the next purchase price of a medicine; both are usually needed to estimate the cost for the full list of medicines. The first option is obtaining data on current medicine prices in the market where the medicines will be purchased. The other option for estimating next purchase price is to adjust the last purchase price for factors such as inflation.

- Calculate cost of each pharmaceutical by multiplying quantity of product by estimated unit cost.
- Then, preparing total pharmaceutical cost requires adding up the estimated cost of all the pharmaceuticals required
- Estimating the cost for procurement (e.g. transportation, perdiem) and the cost required for preparing/printing drug requisition format, stock record card, patient prescription registration book, prescription paper, and consumption reporting formats, etc may also be needed and presented together with direct pharmaceutical purchasing cost or separately.
- The estimated annual pharmaceutical supply cost will be the sum of all costs indicated above. It should be discussed by the staff of the health institution before it is submitted for approval to concerned body.

Step-9: Reconcile estimated pharmaceutical cost (demand) with budget

- In ideal circumstances the budget could be made available to pay for the pharmaceuticals estimated. If the budget available/allocated are still insufficient then the type and quantities of the required must be reviewed and reduced to bring the total ordered quantities with in the budget limit.
- Rational approaches or methods should be used to reconcile need with budget

2. Consumption method

Uses records of past consumption of individual medicines (adjusted for stock-outs and projected changes in medicine use) to project future need.

Consumption method is useful when:

- Historical data on drug consumption exists (accurate consumption data are available or easily obtainable).
- Drug supply at facility has been consistent (stock-out for not more than three months).

- Stock management is reasonably good.
- There is low level of wastage and loss through expiry, damage and theft.
- There is acceptable pattern of prescribing.

Advantages:

- Does not require detailed morbidity data or standard treatment protocol
- Requires less detailed calculations
- Useful for facilities in which their health problems are numerous and drug treatments are complex
- Identifies stock management problems and encourages improvements
- Reliable if consumption is well-recorded and stable

Disadvantages:

- Does not encourage good morbidity recording
- Unreliable if there had been long stock outs (over three months) and high drug wastage or losses
- Doesn't address appropriateness and may not correspond to priorities and needs
- Does not provide a detailed and systematic basis for reviewing drug use by improving prescribing patterns. (May perpetuate irrational drug use)
- May be difficult to obtain reliable drug consumption data especially in new or rapidly changing services

Steps in quantification using consumption method

Step-1: Prepare a list of pharmaceuticals to be quantified

Pharmaceutical list should be prepared or updated as described in the previous chapter.

Step-2: Determine the period of time to be reviewed for consumption

Depending on the purpose of quantification, appropriate period to review consumption data should be determined. If an annual quantification is going to be done, consumption data for a minimum of the past twelve months should be reviewed (if a full year useful data are available). Factors such as seasonal variation need to be considered to select the appropriate timing and duration of consumption data review.

Step-3: Determine quantity or consumption of pharmaceuticals

Option 1: for calculating order quantities for next procurement period

To accomplish this task: average monthly consumption ($\mathbf{C_A}$ or AMC), review or procurement period (R_M), Average lead time (LT), safety stock (SS), stock on hand or inventory (S_i and stock on order (S_o) are needed.

Key definitions:

- **Average monthly consumption**: is the average of the quantities of product used calculated by dividing total quantity consumed to number of months (commonly the most recent three months)
- **Procurement or review period**: is the interval of time between assessments of stock levels to determine if additional stock is needed and hence initiate order or procurement
- **Safety/reserve stock level**: is the additional buffer or reserve kept on hand to protect against stock-outs caused by delayed deliveries, markedly increased demand, or other unexpected events.
- **Lead time**: is the time between ordering a supply up to receiving and availing it for use.
- **Stock on hand/inventory**: is the quantity of usable stock available at a given point in time
- **Stock on order**: is the quantity of a product ordered but not received yet received

NB: These issues are discussed in detail in inventory management section of this module

To calculate order quantities for next procurement period the following steps are followed

1. Calculate the average monthly consumption

$\mathbf{C_A = C_T / [R_M - (D_{OS}/30.5)]}$

C_A= Average monthly consumption, adjusted for stock outs

C_T= Total consumption during the review period, in basic unit (BU)

R_M= Procurement period in months

D_{OS}= Number of days an item was out of stock during the review period

Example: Take Ampicillin 250 mg capsule

Total consumption for six month review period was 89,000 capsules= C_T

The medicine was out of stock for thirty-four days = D_{OS}

Lead time was 3 months

Therefore the average monthly consumption is (C_A):

CA= 89,000/ [6- (34/30.5)] = 18,218

2. Calculate projected average monthly consumption for expected changes in consumption pattern

When using the example of Ampicillin 250 mg capsule, if uses is expected to increase by 5%, then projected average monthly consumption (C_P)= C_AX1.05= 18,218X1.05= 19,129

3. Calculate the safety stock needed

SS= C_AX LT

SS= Safety Stock

C_A= Average monthly consumption

LT= Average Lead Time

This safety stock level should avoid stock-outs, assuming that the item is reordered when only the safety stock remains, the supplier delivers within the projected lead time, and consumption is no greater than average. The safety stock is three months.

Safety stock for ampicillin 250 mg capsules in the example is the projected average monthly consumption multiplied by lead time, 19,129x3=57,387

4. Calculate the quantity of each pharmaceutical required in the next procurement period.

Q_O= CAX (LT+ PP) + SS- (S_i + S_o)

Q_O= Quantity to order before adjustment for losses or program changes

PP= Procurement period

S_i= Stock now in inventory, in BU= 81,000

S_o= Stock now on order, in BU= 58,000

Using the example of ampicillin 250 mg capsules, the quantity to order is:

QO=19,129x (3+6) + 57,387- (81,000 + 58,000)= 90,548

5. Adjust for losses

To avoid stock outs, one should adjust quantification estimates to allow for losses.

If 10% adjustment per year is considered for losses, the allowance would add 9,055 capsules of ampicillin, bringing the total purchase quantity to 99,603

Option 2: for forecasting pharmaceutical requirement for future period

1. Determine recorded consumption of each pharmaceuticals

Recorded consumption = (opening stock + drug received)- (closing stock)

2. Adjust consumption for stock out

Consumption adjusted for stock out

$$= \text{Recorded consumption x} \frac{\text{period in calculation (in days or month ...)}}{\text{period in stock (in days or month ...)}}$$

3. Adjust for other reasons (If needed)
    - Service expansion, losses……..-increment
    - If the recorded consumption includes avoidable wastages-decrement

Step-4: Compile decentralized quantification (if applicable)

Step-5: convert quantities to order pack size

Step-6: Estimate cost for each pharmaceutical and total costs

Step-7: Compare total cost with budget and make adjustment

3. Proxy/adjusted consumption method

- Uses known consumption data from one system 'standard' to estimate the drug needs in a similar or expanded system 'target'.
- When neither consumption method nor morbidity method are feasible, the best option is extrapolating from consumption data of another region health system.
- Can be population based, defining drug use per 1000 population or service based, and defining drug use per specified patient case/inpatient admission.

Basic steps in adjusted consumption method

1. Select the standard system for comparison and extrapolation

   The **standard** and the **target** should **resemble** in terms of:
    - Geography, climate, morbidity pattern
    - prescribing practice, drug supply status

   The standard should have an adequate and uninterrupted drug supply, fairly rational prescribing practice, complete and accurate records of patient contact and inventory movement
2. Develop the pharmaceutical list
3. Establish the time period to be covered in review

4. Review records from the standard system to compile contact or population data
5. Establish the denominator for extrapolation

   E.g. Consumption either be **thousands** of pt contact or inhabitants in the region
6. Determine the consumption rate in the standard system

$$\text{Standard consumption rate} = \frac{\text{standard adjusted annual consumption}}{\text{number of thousands of contacts or inhabitants}}$$

7. Extrapolate the standard system's consumption rate to the target system

   Target consumption rate = (Standard consumption rate) x (Number of thousands of contact or inhabitants)
8. Adjust for expected losses
9. Estimate costs for each drug and total costs and make adjustments

Example

- Estimate **Ampicilline 250mg** required from the standard to the target system based on the following information
- **Standard** system consumption
  - 50,000 inhabitants
  - 32,500 outpatient
  - 6 month total consumption: 89,000 capsule
  - Out of stock: 34 days
- **Target**
  - 80,000 inhabitants
  - Unknown outpatient

Solution:

Step 1: Standard- X

Step 2: Ampicilline 250mg caps

Step 3: 6 month

Step 4: Per **thousand inhabitants** or per thousand **outpatients**

Step 5: SCR

$$\textbf{SCR} = \frac{\textbf{adjusted annual consumption}}{\textbf{no. of thousands of contact or inhabitants}}$$

= (218,617/50,000 **inhabitants**) x 1000= **4,372** per thousand

Or

= (218,617/32,000 **out patients**) x 1000= **6,727** per thousand

Step 6 : Projected requirement

- **Extrapolate** SCR to the target system
- **SCR** X **estimated no. of thousands** of contacts or inhabitants for the target facility
- 4,372 caps per thousand x 80,000 inhabitants
- 349,788 caps ~ 350 **pack**
- **1** Pack= 24.7
- Value of proposed order = 8,645USD

4. Service-level projection of budget requirements

- It uses the average drug procurement cost per attendance or bed-day in different types of health facilities in a standard system to project drug costs in similar types of facilities in the target system.
- Information needed:

- Average number of curative outpatient attendance, non-curative attendance and inpatient bed-days for each type of facility in the source health system.
- The average cost per outpatient attendance, per non-curative attendance and per bed-day in each type of facility.

- This method does not estimate quantities of individual medicines rather it is used to estimate financial requirements

Steps in quantification

1. Establish the categories of facilities and determine the number in each category
2. Determine the patient contact denominators for each type of facility and compile or estimate the average number of patient contacts of each type at each category of facility
3. Calculate the average cost per contact

$$\text{Average cost per contact} = \frac{\text{Total drug purchase}}{\text{Total attendance or bed days}}$$

4. Calculate the total projected drug costs

- ✓ Multiply the average number of patient contact for each facility by the number of facility and average drug cost.

Table 4.1. Comparison of quantification methods

Methods	**Uses**	**Essential Data**	**Limitations**
Consumption	First choice for procurement and future consumption forecasts, given reliable data	Reliable inventory records, Records of supplier lead time, Projected drug costs	Must have accurate consumption data can perpetuate irrational use
Morbidity	Estimating need in new programs or disaster assistance, Comparing use with theoretical needs, Developing and justifying budgets	Data on population and patient attendance; Actual or projected incidence of health problems; Standard treatment; Projected drug costs	Morbidity data not available for an diseases; Standard treatments may not really be used
Adjusted consumption	Procurement forecasting when other methods unreliable; comparing use with other supply system	Comparison area or system with good per capita on consumption, patient attendance, service levels and morbidity; Number of local health facilities by category; Estimation of local user population broken down by age	Questionable comparability of patient population morbidity and treatment rate
Service Level projection of budget requirements	Estimating budget needs	Utilization by service levels and facility type; Average drug cost per attendance	Variable facility attendance treatment pattern supply system efficiency

4.6. Methods of reconciliation of pharmaceutical budget with demand

There most common types of reconciliation of pharmaceutical budget with demand

- VEN analysis
- ABC analysis
- Therapeutic category analysis

VEN analysis

- It is an approach in which pharmaceuticals are divided according to their health impact in to vital, essential and non-essential/normal-use categories.
    - V: Vital- potentially lifesaving, have significant withdrawal effect (making supply mandatory), or are crucial to providing basic health services. mandatory to be available 24 hours of a day, 7 days of a week, and twelve months of a year.
    - E: Essential- effective against less severe but nevertheless significant forms of illness, but not absolutely vital to providing basic health services. This pharmaceuticals are mandatory to have at least once a day, or at least once in a week, or at least once in a month or once in a quarter of the year, but not as highly mandatory as vitals
    - N: Nonessential- used for minor or self-limiting illnesses
- NB:
    - Drug ordering and stock monitoring should be directed at vital and essential drugs.
    - Safety stocks should be higher for vital and essential items.
    - VEN should be used to ensure that enough quantities of vital and essential pharmaceuticals are bought first.
    - Only reliable suppliers should be used for vital and essential drugs.

ABC analysis

- ABC analysis is the method for determining and comparing drug cost.
- It identifies three useful tiers for analysis:
    - Class A items: highest annual usage (high volume or high cost)
        - Usually accounts for 10-20 percent of items ordered and 70 to 80 percent of funds.
    - Class B items: moderate annual usage
        - Accounts 10 to 20 percent of items ordered and 15 to 20 percent of funds.
    - Class C items: Lowest annual usage
        - Accounts for 60-80 percent of items ordered and 5-10 percent of funds.
- After ABC analysis, careful evaluation of class A items should be done. If pharmaceutical cost is needed to reduced, the focus should be on class A items. During procurement, competitive approaches should be used and all possible efforts should be sought to get lower price for such items.

Therapeutic category analysis

- ✓ Its applications are the same as those of ABC analysis. We should focus on cost-control efforts on the therapeutic categories that show the highest consumption and greatest expenditures. In this approach, therapeutic categories having the consecutive highest expenditures are identified and the possible change in therapeutic strategy that might prove to be cost-effective will be looked for.

The details of these analyses will be discussed under inventory management section.

Students' Activity # 1

Activity type: Exercise

Activity topic: pharmaceutical quantification

Activity detail: you are provided with five exercises here below to practice quantification. Follow the necessary steps and accomplish the required tasks.

Exercise 1:

There was an ending balance of 169,000 tablets of chlorpropamide 250 mg. The lead time is ninety days, the total consumption for the past six months was 162,000 tablets, and the procurement period is six months. Based on the information given above, calculate the following:

a) Average monthly consumption.
b) Projected average monthly consumption.
c) Safety stock.
d) Quantity to order (packs).
e) Adjusted quantity for losses.
f) Total costs.

(N.B: pack size= 1,000; use adjustment= 5%; loss adjustment= 10%; probable pack price= 27.90 USD)

Exercise 2:

Drug "X" is available in tablet formulation of 500mg strength. It is used for the treatment of three diseases (A, B and C). The average amount of the drug needed per course of treatment was 20 tablets for disease "A", 20 tablets for disease "B" and 10 tablets for disease "C" (assume the average treatment schedule is the same for all group of patients). The total number of treatment episodes (number of cases who need drug treatment) per year in a given hospital were 500 (disease "A"), 2000 (disease "B") and 1000 (disease "C"). If one box contains 100 strips of 10 tablets, calculate:

- The total quantity of the drug needed in box unit (consider 5% allowance).

Exercise 3:

In 2007 E.C, an average monthly consumption for 150mg chloroquine phosphate base was 1600 tabs. A local NGO promised to supply 6 tins of 1000 tabs of chloroquine for the health center in the first quarter of 2008 E.C and 1000 tabs of the drug is available at the end of the fiscal year

2007 E.C. From experience it is known that the time taken between the initiation of the order & arrival of the drugs in stock has been in the average one & half months. Estimate the quantity of chloroquine needed by the health center for the year 2008 E.C.

Exercise 4

Estimate the total quantity of medicines required for the treatment of **acute tonsillitis** based on the following information.

- **Last** total No. of contacts (C)= 3,123,408
- 5% expected **rate** of **increase**
- **Frequency** of **acute tonsillitis** (per thousand) = (72 for <5, 33 for >5)
- **P_T=** 100% for all treatment options

Treatment for **acute tonsillitis**

Under 5 - Penicillin VK 125 mg/5 mL liquid (BU=ml) 5ml po QID for five days
-Paracetamol solution 120 mg/5 Ml (BU=ml) 1.5ml po QID for ten days
Above 5 -Procaine penicillin 3 MU injection (BU=Vial) 1 vial stat
-Penicillin VK 250 mg (BU=Tablet) 1 tab po QID for five days
-Paracetamol 500 mg (BU=Tablet) 2 tab po QID for five days

Exercise 5

The following table shows stock movement of Doxycycline 100mg tablet as obtained from a bin card and stock out recording form in health center "X" for one year (consumption is in tablet).

Date	Received from supplier	Issued/consumed	Balance
1 Sep	-	-	5000 (opening stock)
5 Sep	-	4000	1000
25 Oct	5000	-	6000
15 Nov	-	2000	4000
20 Dec	-	2000	2000
15 Jan		1000	1000
28 Jan	-	1000	0
By 10th February the drug was totally out of stock in the health center			
10 March	6000	2000	4000
28 April	-	1000	3000
4 June	-	2000	1000
10 July	3000	-	4000
15 July	-	2000	2000

30 Aug	-	-	2000

Calculate quantity of Doxycycline 100mg tablet required for next year in box unit using the data above:

- Assume the number of days per month is 30 in all months (as in Ethiopian calendar)
- Consider 3% allowance for expected increment in next year consumption
- 1 box contains 100 strips of 10 tablets each

Chapter summary

- Pharmaceutical quantification is the process of determining the amount of pharmaceutical products needed for the purpose of procurement.
- Quantification is important for informing supply chain decisions on product selection, financing, procurement, and delivery.
- No matter which pharmaceuticals a program distributes, a quantification exercise follows three key steps: preparation, forecasting, and supply planning.
- There are four basic methods for estimating pharmaceutical quantities which morbidity method (patient morbidity standard treatment method), consumption method, adjusted consumption method (proxy consumption method), service-level projection of budget requirements.
- VEN and ABC analysis either alone or together are used to reconcile pharmaceutical cost requirement with actual budget.

References and further reading

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Chapter 5: Pharmaceutical Procurement

Chapter Description

This chapter includes basic concepts of pharmaceutical procurement and operational principles of the procurement process. In addition, Common procurement challenges and Procurement rules and regulations in Ethiopia will be also addressed.

Chapter objectives

At the end of this chapter, students are able to:

- Explain the basic concepts of pharmaceutical procurement
- State the operational principles of good pharmaceutical procurement
- Identify factors affecting cost of pharmaceuticals
- Discuss the pharmaceutical procurement process
- Describe pharmaceutical procurement methods
- Identify common challenges related to pharmaceutical procurement
- Describe the pharmaceutical procurement rules and regulations in Ethiopia

5.1. Introduction

Pharmaceutical procurement is the process of acquiring drug products through purchase, manufacture, or donation. It is a major determinant of pharmaceutical availability and the total health cost. Pharmaceuticals may be acquired through purchase, donation, manufacture, or other mechanisms. Procurement is only one of several elements of pharmaceutical supply management but can be the function that takes up much of the time of pharmacists. It is a complex process that involves many steps, agencies, ministries, and manufacturers. The pharmaceutical procurement system is a major determinant of pharmaceutical availability and total pharmaceutical costs. In most developing countries, pharmaceutical purchases represent the single largest health expenditure after personnel costs. Pharmaceuticals also consume the major share of health-related foreign currency exchange. Usually, existing government policies, rules, and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market. In many countries, public health officials have limited experience in designing an optimal

procurement system to fit their market context. An effective pharmaceutical procurement process should;

- ✓ Seek to manage the buyer-seller relationship in a transparent and ethical manner
- ✓ Procure the right medicines in the right quantities
- ✓ Obtain the lowest practical purchase price
- ✓ Ensure that all procured pharmaceuticals meet recognized standards of quality
- ✓ Arrange timely delivery to avoid shortages and stock-outs
- ✓ Ensure supplier reliability with respect to service and quality
- ✓ Set the purchasing schedule, formulas for order quantities, and safety stock levels to achieve the lowest total cost of purchasing at each level of the system.

Given the impact of procurement activities on the operation and effectiveness of health services, procurement activities must be performed by competent staff using sound procedures, working in adequate offices with good communications, and with access to reliable inventory and consumption information. Good procurement management also demands medical, pharmaceutical, managerial, financial, and often political expertise.

5.2. Strategic objectives of pharmaceutical procurement

There are four strategic objectives of pharmaceutical procurement set by WHO.

1. Procure the most cost-effective drugs in the right quantities

The first strategic objective is that all organizations responsible for procurement, whether they are public, private non-profit, or private for-profit, should develop an essential medicines list to make sure that only the most cost-effective drugs are purchased. Procedures must also be in place that accurately estimates procurement quantities in order to ensure continuous access to the products selected without accumulating excess stock.

2. Select reliable suppliers of high-quality products

The second objective is that reliable suppliers of high-quality products must be (pre-)selected and that active quality assurance programs involving both surveillance and testing must be implemented.

3. Ensure timely delivery

The third strategic objective is that the procurement and distribution systems must ensure timely delivery of appropriate quantities to central or district stores and adequate distribution to health facilities where the products are needed.

4. Achieve the lowest possible total cost

The fourth objective is that the procurement and distribution systems must achieve the lowest possible total cost, considering four main components:

- ✓ The actual purchase price of drugs;
- ✓ Hidden costs due to poor product quality, poor supplier performance, or short shelflife;
- ✓ Inventory holding costs at various levels of the supply system; and
- ✓ Operating costs and capital loss by management and administration of the procurement and distribution system.
- ✓ Opportunity costs

5.3. Operational principles for good pharmaceutical procurement

1. Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers, and adjudication of tenders) should be divided among different offices, committees and experts, each with the appropriate expertise and resources for the specific function (separation of function)

Senior managers responsible for procurement must ensure that pharmaceutical procurement is carried out effectively, efficiently, and in accordance with the country's policies, laws and regulations. The health system's procurement office, under various names, is normally responsible for actually managing the procurement function. The procurement office should be responsible for coordinating inputs to achieve the desired result. But in most public sector contexts the reality is that all functions of the drug procurement process are entirely in the hands of one office or official. Without appropriate separation of function and authority, the procurement process is much more susceptible to influence by special interests. In that case, procurement personnel may be able to bias drug selection, manipulate orders to increase the quantities of certain drugs, prejudice supplier qualification decisions, manipulate the final award

of the tender, and slant product specifications to limit competition. The separation of key functions contributes to professionalism, accountability, and an efficient procurement system.

2. **Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.**

Fairness and the perception of fairness are essential to attract the best suppliers and achieve the best prices. When the pharmaceutical tender process is less transparent and even secretive, it tends to be perceived as corrupt or unfair. There may be accusations of unfair influences. Whether true or not, such charges are damaging and suppliers, health care providers, and the public lose confidence in the system. Unsuccessful suppliers may feel that they have no chance of winning and consequently withdraw from future tenders. As the pool of potential suppliers decreases to a small set, price competition decreases and procurement prices become much higher than necessary.

3. **Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.**

In order to ensure that drugs are available where and when they are needed, drug procurement must be carefully planned. Planners should consider factors such as access to suppliers; funding availability and timing; the number of levels in the logistics system; constraints of time and resources affecting procurement activities such as reviewing drug selection, quantification, tendering, and contracting; the lead times at various levels of the system; import procedures; customs clearance; and access to transport.

4. **Public sector procurement should be limited to an essential drugs list or national/local formulary list**.

No public or private health care system in the world can afford to purchase all drugs circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly purchased and is one of the most effective ways to control drug expenditure.

A nationally developed formulary or selection based on the essential drugs concept has been used in both industrialized and developing countries' health systems for more than twenty years. This allows the health system to concentrate resources on the most cost-effective and affordable drugs to treat prevailing health problems. The selection of drugs based on a national formulary or

national list allows for concentrating on a limited number of products. Larger quantities may encourage competition and lead to more competitive drug prices. Reducing the number of items also simplifies other supply management activities and reduces inventory holding costs.

5. **Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.**

The INN is widely accepted as the standard for describing drugs on a procurement list or tender request. Although this is most obviously applicable when purchasing drugs that are available from multiple sources, the generic description should also be used when purchasing single-source products. When purchasing products that present potential problems with pharmaceutical equivalence or bio-equivalence the procurement request should specify the quality standards but not mention specific brands.

6. **Order quantities should be based on a reliable estimate of actual need.**

Accurate quantification of procurement requirements is needed to avoid stock-outs of some drugs and overstocks of others. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated-quantity supply contract. When funds are not available to purchase all drugs in the quantities which were estimated to be needed, it is necessary to prioritize the procurement list to match available financial resources. Various techniques such as VEN (vital, essential, and nonessential) Analysis, and ABC Analysis can be used to select priorities and reduce the quantities of less cost-effective drugs.

7. **Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.**

Potential sources of funds for pharmaceutical procurement include government financing, user fees, health insurance, community co-financing, and donor financing. These options vary in terms of efficiency, equity, and sustainability. The most important considerations for procurement are total funds available, adequate access to foreign exchange, and the regularity with which funds are available. It is the responsibility of governments and senior managers to establish appropriate and reliable funding for public drug procurement as a high priority and to implement mechanisms that provide adequate funding on time to support public sector procurement.

Efficient financial management systems are especially important if funds are limited and procurement priorities must be set. Being able to order drugs when needed and to pay for them on delivery has a very positive effect on reducing both prices and stock-outs and on increasing supplier confidence in the procurement system. Prompt, reliable payment can have as great an influence on bringing down drug prices as bulk discounts.

8. **Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.**

Larger procurement volume makes favorable prices and contract terms more likely, by increasing suppliers' interest in bidding and by providing them with an incentive to offer a competitive price. A higher volume for single items may be achieved through pooling of procurement volume from many facilities or several states or countries, by restriction of the drug list or by elimination of duplication within therapeutic categories.

9. **Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.**

There are four main methods for purchasing drugs. Three of them are competitive: restricted tenders, open tenders, and competitive negotiations. The fourth method is direct negotiation with a single supplier. Since inducing supplier competition is a primary key to obtaining favorable pricing, the public sector should use competitive methods for all but very small or emergency purchases. This assumes, of course, that there are multiple suppliers for the items needed.

As long as drug quality and service reliability are assured, competition should be increased to the point at which drug prices are as low as possible. The "rule-of-five" for pharmaceutical pricing holds that generic prices generally reach their minimum when there are at least five generic alternatives on the market and that prices in tendering systems are at their lowest where there are at least five bids per item; adding more bids generally does not result in further lowering of prices.

10. **Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.**

Except in those systems where each health facility negotiates prices and purchases drugs individually, public pharmaceutical procurement systems are seen as purchasing groups. Normally, group purchasing achieves lower prices than would be available to the same group of health facilities if they purchased individually. These discounts are based on the fact that

facilities that are part of the purchasing group will purchase contract items only from the selected contract supplier, as long as that supplier can perform. This is called sole-source commitment. If group members are free to make separate deals for contract items with other suppliers at will, the suppliers who participate in tenders will have little incentive to offer the best possible discounts to the purchasing group.

11. Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process that considers product quality, service reliability, delivery time, and financial viability.

Pre and post-qualification procedures help to eliminate substandard suppliers if properly managed. Pre-qualification is the procedure of evaluating supplier capacity and reputation before bids are solicited for specific products. This is the preferred procedure, especially for ongoing drug procurement systems. Although substantial time is required to establish an initial list of pre-qualified suppliers, once this has been done the lowest pre-qualified tenderer for each product is deemed to be qualified, which expedites adjudication and contract award. Post-qualification evaluates the suppliers after bids have been received. If there are numerous offers from unknown suppliers there may be long delays in awarding contracts, as it will be necessary to validate suppliers' capacity to supply good-quality products.

12. Procurement procedures/systems should include all assurances that the drugs purchased are of high quality, according to international standards.

The selection of suppliers that are known to provide high-quality products is the primary key to ensuring drug product quality. When using new suppliers whose products are not familiar in the country, the procurement system must be particularly alert to product quality issues. Four components make up an effective quality assurance system:

- Selecting reliable suppliers of quality drugs;
- Using existing mechanisms, such as the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce;
- Establishing a program for reporting product defects; and
- Performing targeted quality control testing.

5.4. Factors influencing pharmaceutical unit prices and total costs

Given the limited budgets of virtually all health programs, pharmaceutical procurement costs must be a concern of all policymakers, senior officials, essential medicines program managers, and procurement staff. Pharmaceutical procurement costs include several different components; some costs are obvious and some are not.

- **Unit prices**

There are many considerations involved in pharmaceutical pricing by manufacturers and distributors, and many factors that cause prices to vary from country to country. A fundamental principle is that increasing competition among suppliers and products usually decreases pharmaceutical prices. Several factors influence competition and pricing in any pharmaceutical market. One issue is how many different drug products and different generic versions of the same product are on the market. The "rule of five" in pharmaceutical pricing says that in general the lowest competitive prices are available when five or more generic alternatives for a particular product are available or when, in a tender, there are at least five bids per item. These factors can be influenced by government policies on registration, licensing for manufacturing and distribution, authority to prescribe and dispense, generic substitution, and price control.

- **Reorder frequency and the total cost of purchasing**

Pharmaceutical acquisition prices are only one part of the total cost of pharmaceutical purchasing; the other important components are the costs associated with holding inventory, the costs of operating the purchasing system, and the extra costs incurred when stockouts occur (shortage costs). Although procurement offices typically concern themselves mainly with pharmaceutical acquisition costs, the other cost components may increase the total purchasing cost by 50% or more of the acquisition costs. For each country's situation, total purchasing costs can be minimized by choosing the optimal reorder frequency model, as defined by;

- The interval between order; options include **annual** (one order per year), **scheduled** (periodic orders, for example, every three months), and **perpetual** (orders are placed whenever stock falls to a specified level). Systems minimize costs by striking the right

balance between the various elements less frequent ordering decreases procurement process costs but increase inventory holding costs

- Safety stock targets; which vary according to supplier lead times, patterns of consumption, and service level objectives.
- The formula used for calculating the order quantity; which may be fixed or variable.

❖ **Visible and hidden costs**

The total procurement cost has four components pharmaceutical acquisition prices, inventory-holding costs, purchasing operations costs, and shortage costs. Some of these costs are easily visible to managers the total expenditures for pharmaceutical acquisition or the salaries of procurement staff. The potential impact of hidden costs on the pharmaceutical procurement total cost can be very profound. The quoted price might be lower but additional expenses resulting from poor performance may ultimately raise the total cost significantly. However, the costs associated with shortages and poor supplier performance are not so obvious; hidden costs associated with poor performance by the supplier or the procurement office include;

- Increased acquisition costs due to emergency procurement, such as when a vital medicine is ordered too late or usage exceeds estimates or the supplier fails to deliver on time
- Replacement costs when goods are lost or must be discarded because of poor packaging, improper shipping conditions, rapid spoilage, or short shelf life
- Replacement costs for short shipments, wrong concentrations of liquid preparations, wrong dosage forms, and so on
- Storage, port charges, and administrative expenses due to inefficient clearing procedures or lack of funds or proper documentation
- Health and economic costs of stockouts resulting from delay or default on delivery

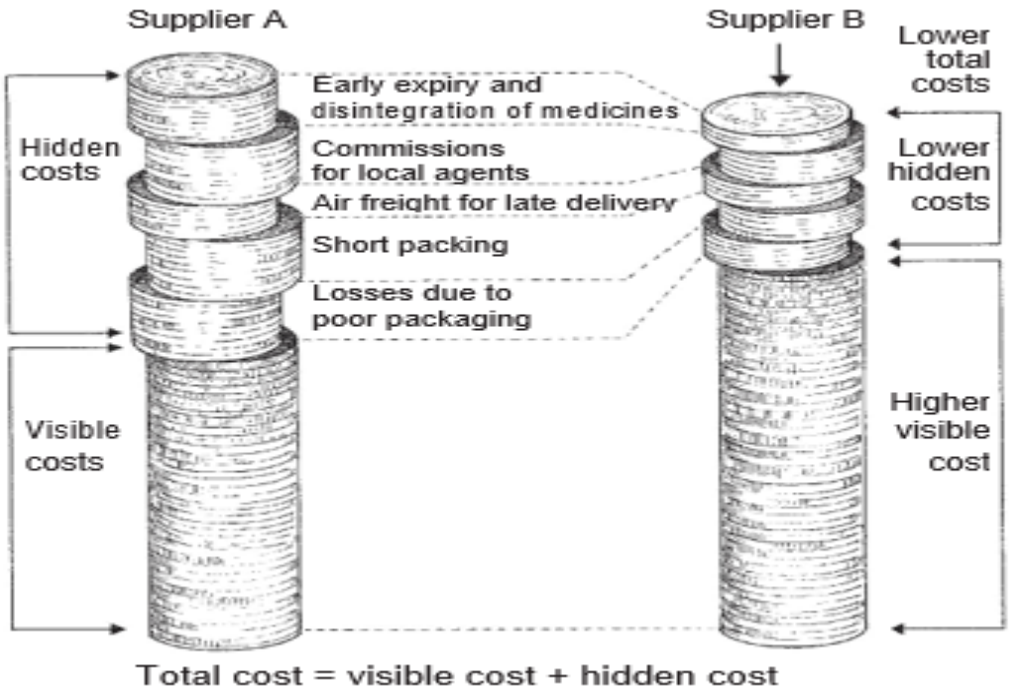

Figure 5.1: The impact of hidden cost on the total cost

5.5. Pharmaceutical procurement process

Pharmaceutical procurement composes different activities stated in the following figure.

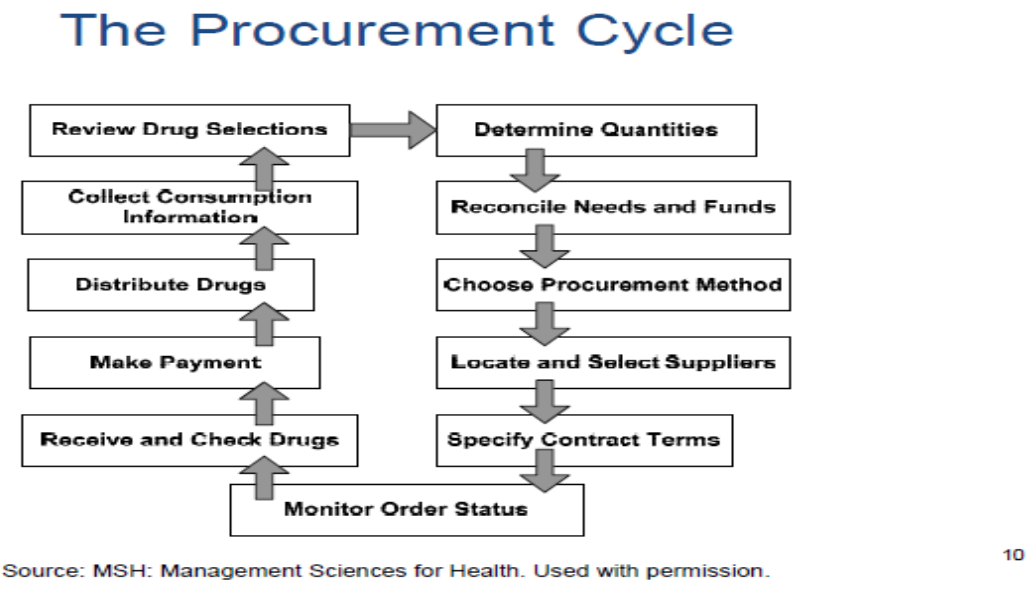

Figure 5.2: Pharmaceutical procurement cycle

1. **Identify what to procure:** You have to review the selected drugs each time you begin the procurement process. Give priority to vital and essential medicines.
2. **Determine how much to procure:** Obtain the quantified amounts of pharmaceuticals from the step of quantification.
3. **Reconcile Needs and Fund/Budget:** Estimate the cost of the quantity of pharmaceuticals to be procured. The estimated quantity of pharmaceuticals needed may exceed the available pharmaceuticals budget of the health facility. If this happens, we have to adjust the type and quantity of pharmaceuticals systematically, i.e., using the VEN system or ABC Value Analysis.
4. **Determine when to Buy:** It is about preparing a procurement timetable that indicates the date on which each activity has to be performed. It helps in monitoring and making follow-ups of the order status. In proper procurement, planning considers factors like lead time, demand fluctuations… etc, which have an impact on determining the time of purchase.
5. **Locate and select suppliers:** This involves determining the tender format or making use of procurement methods in order to select and locate suppliers.
6. **Prepare tender documents/Tender invitation/ specify contract terms:** It is a document that lays down the technical and basic legal requirements for obtaining products of acceptable quality. It serves as a reference if problems with suppliers arise. The decision on the final format of the tender invitation will have to take into account; the prevailing policies and needs regarding the procurement of drugs.
7. **Evaluation of Bids:** After thoroughly evaluating the bids, a special committee or tender board usually awards the tender. It is important that a pharmacist or a person with technical knowledge of pharmaceutical products and their manufacturer be a member of the tender board. As is often the case, the determining factor for awarding a tender is price. Quality must be a more important consideration due to the fact that substandard products give rise to health hazards as well as financial losses to the procurement agency.
8. **Prepare purchase order/Requisition**: This form specifies among other things; the generic name, strength dosage form, of the drug, unit monthly consumption, quantity in stock, quantity requested (to be filled by the purchaser) and the quantity supplied, unit cost and total cost (as per the tender agreement). It also specifies the supply period and full address of the two parties.

9. **Monitor order status**: Once the pharmaceutical request or purchase order is placed, the progress of the order must be closely monitored. Recording of the date on which the requisition is prepared; approval sent to the supplier, and previous supplies received must be kept in order to react when there is unnecessary delay.
10. **Receive and check drugs**: Check for the type and quantities received against the pharmaceutical requisition and invoice. Besides, we have to check the quality, packaging, and labeling of the products in order to verify whether they meet the required standards. Report any discrepancy in quantity or quality to the supplier. The quality problem should also be reported to the drug administration and control department.
11. **Make payment as per contract**: we have to pay the amount of money or assets we agreed to pay within the contract.
12. **Update the balance of the budget:** Once the purchased drug and inventory control are received, subtract the cost of them from the previous balance in order to know the current status of the drug budget.

5.6. Pharmaceutical procurement methods

In some countries, existing laws and regulations need to be amended to more adequately address important issues that include the following:

1. Whether the tender should be open or restricted to prequalified suppliers,
2. The tender period, and
3. How the quantities to be purchased are estimated.

The major pharmaceutical procurement methods used by health systems are open tender, restricted tender, competitive negotiation, and direct procurement, which vary with respect to their effect on the price, delivery times, and workload of the procurement office.

- **Open tender**

Open tendering is a formal procedure by which quotations are invited from any supplier's representative on a local or worldwide basis, subject to the terms and conditions specified in the tender invitation. Assessment of suppliers in an open tender can be time-consuming because of the large number of bids. As a result, too many offers may be submitted that overload the limited

capacity of procurement agencies and the assessment of suppliers and bids may not get done as thoroughly as they should.

- **Restricted tender**

A restricted tender, open only to prequalified suppliers. In a restricted tender, interested suppliers must be approved in advance, often through a formal prequalification process that considers adherence to good manufacturing practices, past supply performance, financial viability, and related factors. The prequalification process is often open to any supplier that wishes to apply. In restricted tender, since it is open only for pre-qualified suppliers could provide a better system for quality assurance (product quality may be more easily assured) than an open tender. Since the pre-qualification of suppliers is done independently of the evaluation of prices of the products the supplier assessment can be done more objectively. With a restricted tender, pre-qualification can be done continuously as prospective suppliers express their interests and before tenders are conducted.

- **Competitive negotiations**

In competitive negotiation, the buyer approaches a limited number of selected suppliers (typically at least three) for price quotations. Buyers may also bargain with these suppliers to achieve specific price or service arrangements. Usually, this procurement method is used primarily in the private sector, because public-sector procurement organizations are generally forbidden from negotiating or bargaining with suppliers. For example, global organizations such as UNICEF, the Clinton Foundation, and SCMS have successfully negotiated reduced prices of antiretroviral (ARV) medicines with manufacturers. Usually, this method results in higher prices.

- **Direct procurement**

This is the simplest but perhaps the most expensive procurement method of all as it involves direct purchase from a single supplier either at quoted prices or negotiated prices. This method is well suited for emergency situations but is not the preferred choice for routine orders.

Table 5.1: advantages and disadvantages of pharmaceutical procurement methods

Method	Advantages	Disadvantages
Open tender	♦ Many bids, some with low prices ♦ New suppliers can be identified	♦ High workload is required in evaluation of bids and selection of suppliers
Restricted tender	♦ Fewer bids (less workload than open tender ♦ Quality easier to ensure	♦ More limited options ♦ System for prequalification must be set
Competitive negotiation	♦ Suppliers are generally well known ♦ Less evaluation work	♦ Higher price
Direct procurement	♦ Easy and quick	♦ Higher price

5.7. Challenges of pharmaceutical procurement

To achieve the many benefits of an efficient procurement process, you need to understand the potential obstacles you are likely to encounter. Here are some of the common procurement challenges your organization may be facing.

♦ **Suspicion of Fraud or Theft**

Sometimes the lack of available inventory is not the result of insufficient purchasing, but rather a theft or fraudulent misuse of supplies. For example, you could have employees with substance abuse problems stealing drugs, or individuals selling medicines or equipment to third parties for profit. When inventory goes missing, your purchasing costs increase, and you have more difficulty measuring actual demand and usage.

To address this challenge, it is critical to have processes in place for identifying individuals who may be likely to commit fraud or theft, ideally before they are hired. Relying on effective background screening and continuous workforce monitoring can help manage these risks and protect your workplace and inventory.

♦ **Changing Regulatory Requirements**

Any changes in federal and state regulations can impact the equipment and medicines you must keep on hand and the services you need to maintain smooth operations. In addition, to maintain accreditation status, you must stay in compliance with those guidelines. As a result, you need resources and trusted managed service providers to help you monitor regulatory compliance developments and apply best practices for ongoing compliance.

- **Paper-Based Processes**

When you order, receive, and distribute inventory based on manual workflows, you can experience delays and bottlenecks in delivering critical supplies. However, one great way to address these outcomes is through automation. For example, an e-procurement solution can provide greater visibility into inventory availability, ordering, and delivery timelines. With data and analytics from an automated solution, you can see what supplies and equipment you have and where inventory is falling. You can also anticipate future purchasing needs and establish more realistic budgets.

- **Limited Supplier Network**

When patient demand is steady and predictable, it is often easy to get the products and services you need in a timely manner. But when demand increase, as it has through the many surges of the pandemic, relying on few suppliers can expose your organization to frequent delays and stockouts. To address this challenge, it is critical to examine your existing suppliers to be sure your preferred providers can scale to meet your evolving needs. If suppliers seem to be barely keeping up or don't offer solutions to help you meet your shifting needs, it may be time to look at other providers. Besides, the following are the other common challenges of pharmaceutical procurement

- Inadequate rules, regulations, and structures;
- Public sector staff with little experience in responding to market situations;
- Absence of a comprehensive procurement policy;
- Government funding that is insufficient and/or released irregularly;
- Donor agencies with conflicting procurement regulations;
- Fragmented drug procurement at the provincial or district level;
- Lack of unbiased market information;
- Lack of trained procurement staff.

5.8. Procurement rules and regulations in Ethiopia

According to the Ethiopian Public Procurement Proclamation (No 649/2009), procurement means "acquiring of goods, works, consultancy or other services through purchasing, hiring or acquiring by any other contractual means." In particular, the aim of the procurement is in order to acquire goods, works, consultancy services, and other services at the right quality, in the right quantity, from the right sources, at the right time, place, and price to achieve organizational objectives.

Starting from 1991, Ethiopia's financial issues were regulated by financial proclamation No.57/1966 and the Ministry of Finance (MOF) was the responsible government body for regulating the country's procurement system. A few years later the country tried to address major shortcomings noticed in the previous country's public procurement process through different financial and legal techniques. Some of the attempts took include; the government ratified the financial regulations no.17/1997 which deals with procurement principles and Ministry of Finance directives about procurement and other related issues in 1997; and a draft "procurement manual" was prepared, in 1999, by Minister of Finance as a part of dealing weakness identified in the previous procurement system. Even though the previously mentioned procurement process regulations were passed, different assessments conducted on the public procurement practice of the county showed that different weaknesses and gaps were still present. By considering those weaknesses the Federal Government of Ethiopia Procurement and Property Administration Proclamation No 649/2009 were issued by parliament, which is supported by different procurement manuals and directives published, in 2010.

The current federal public procurement directive was issued to replace the Ministry of Finance and Economic Development Procurement Directive issued in July 2005. This federal public procurement directive has 52 articles and is legally enforceable since the 8th day of June 2010. This directive is used to regulate any procurement carried out by any public body including the Ethiopian Pharmaceutical Supply Agency (EPSA), which is the public pharmaceutical purchaser and distributer to public health facilities in Ethiopia.

Students Activity # 1

- Review Ethiopia Federal Public Procurement Proclamation and Directive from Pharmaceutical Procurement Perspective (hint: articles that could pose challenge for reliable pharmaceutical procurement.)

5.9. Monitoring and evaluation of pharmaceutical procurement performance

Tracking key aspects of procurement and taking the necessary corrective actions result in continuous improvement of the system's effectiveness. Procurement should be monitored and evaluated against its objectives using appropriately designed indicators. The following indicators can be used to measure the performance of procurement.

1. **Procurement efficiency:** This indicator measures the efficiency of procurement practices by comparing the prices paid for medicines with international price standards. Formula for computing this indicator is;

$$\textbf{Procurement efficiency} = \frac{\textbf{Median price of products procured}}{\textbf{International median reference value}}$$

2. **On –Time Delivery:** This indicator measures the percentage of all orders delivered by the requested delivery date, as indicated in the purchase order or contract during a defined period of time. The Formula for calculating this indicator is;

$$\textbf{On-time Delivery} = \frac{\textbf{Number of orders delivered within requested period x 100}}{\textbf{Total number of orders delivered}}$$

3. **Percentage of orders fully comply with essential medicine list:** This indicator evaluates the percentage of requisitions made for medicines only within the essential medicine list. Formula for determining this indicator is

$$\textbf{\% of orders fully comply with EML} = \frac{\textbf{Number of orders fully comply with EML x 100}}{\textbf{Total number of orders delivered}}$$

4. **Supplier Fill Rate:** This indicator measures supplier's ability to fill orders completely in terms of items and quantity as defined in purchase order or contracts, during a definite period of time. The formula is;

$$\textbf{Supplier Fill Rate} = \frac{\textbf{Number of Orders Filled Correctly}}{\textbf{Total Number of Orders}} * 100$$

- The other indicators that can be used for measuring the pharmaceutical procurement performance include;
  - Adherence to procurement time table
  - Percentage of procurement with defective products
  - Average lead time of the supplier and
  - Others

Chapter summary

- Pharmaceutical procurement is a process by which products are acquired through the purchase, manufacture, or donation.
- The availability of pharmaceuticals and the cost of health care are heavily influenced by it.
- Given the impact of procurement activities on the operation and effectiveness of health services, procurement activities must be performed by competent staff using sound procedures, working in adequate offices with good communications, and with access to reliable inventory and consumption information.
- A pharmaceutical procurement process should procure the right medicines in the right quantities, obtain the lowest practical purchase price, ensure all procured pharmaceuticals meet quality standards, and arrange timely delivery to avoid shortages and stock-outs.
- A successful pharmaceutical procurement requires the implementation of basic operational principles.
- If you want to achieve the many benefits of an efficient procurement process, you need to understand the obstacles you may encounter and how you can overcome them.

References and further reading

1. Management Sciences for Health. MDS-3: Managing Access to Medicines and Health Technologies. 3rd ed. Arlington, VA: Management Sciences for Health, Inc; 2012.
2. World Health Organization. Operational principles for good pharmaceutical procurement. Geneva: World Health Organization; 1999

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CHAPTER 6: DISTRIBUTION AND TRANSPORTATION

Chapter objective

At the end of this chapter the students will be able to:

- Define distribution management
- Discuss good distribution practice and its purposes
- Discuss transportation management

6.1 Distribution of pharmaceuticals

The primary distribution management goal is to maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed, while ensuring that resources are being used in the most effective way. Distribution costs, which include costs related to storage and transportation, are a significant component of the expense of running a public health supply system. Transportation costs alone can represent a significant percentage of the value of medicines distributed to remote locations. Designing a system for storing and distributing pharmaceuticals, medical supplies, and equipment is complex and important.

Effective pharmaceutical distribution relies on good system design and good management. A well-designed and well-managed distribution system should—

- Maintain a constant supply of medicines
- Keep medicines in good condition throughout the distribution process
- Minimize medicine losses caused by spoilage and expiry
- Maintain accurate inventory records

- Rationalize medicine storage points
- Use available transportation resources as efficiently and effectively as possible
- Reduce theft and fraud
- Provide information for forecasting medicine needs
- Incorporate a quality assurance program

6.2. Good distribution practice and its purpose

The primary distribution management goal is to maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed while ensuring that resources are used in the most effective way. Distribution costs, including storage and transportation costs, are a significant expense of running a public health supply system, often second only to personnel costs. Transportation costs alone may exceed the value of the medicines distributed to some locations, especially in countries with low population densities that cover large geographical areas. Reducing these costs can mean that more money is available for medicine purchases and clinical care. A good distribution system is a cost-effective system that provides an acceptable level of service.

Public health authorities are rarely in a position to create a pharmaceutical distribution system from the ground up; rather, the challenge is to evaluate and improve existing systems. In many public health systems, senior officials do not consider pharmaceutical distribution a high priority; it is too often placed in the hands of poorly trained and inexperienced staff members who are given responsibility but little authority. Under such circumstances, management tends to react to problems and crises rather than take a long-term, strategic view. For example, to save money, a decision may be made to close an apparently costly warehouse, without considering the potential result of increased costs in other areas, such as transportation.

In planning distribution systems to maximize service while minimizing total cost, it is important not to fall into the trap of improving one part of the system to the detriment of the overall system. In the example above, reducing the number of warehouses will decrease operating and inventory

costs. However, with fewer warehouses, transport costs for both the central medical stores and hospitals are likely to increase because of the greater distance to travel to either deliver or collect

supplies; therefore, the distribution planner will want to ensure that warehouse and inventory savings are not negated by the increase in transport costs.

The effect on customer service will also have to be considered. Inventory costs may be reduced, but if customers must wait longer to receive supplies or if availability deteriorates, broader health system objectives will be undermined. This concept of trade-offs and searching for overall system improvement is important for distribution system planners to understand and apply.

Ideally, a public sector with inefficiencies in its distribution system would perform a wholesale evaluation of the existing structure to find solutions that would be optimal for the entire supply and broader health system. To do this, however, requires that the government deem the distribution function important and make available sufficient financial and expert human resources to conduct the technically demanding strategic reviews. Whereas in some situations existing management will be able to conduct such reviews, in many cases management will have neither the time nor the required expertise to carry them out. Therefore, public health authorities may find it more efficient to appoint specialized consultants.

Health programs are frequently managed by well qualified health personnel who lack logistics experience. Logistics is defined here as the ―science (and art) of getting the right amounts of the right things to the right places at the right time. Warehouse and transport managers, storekeepers, and drivers may possess these skills but may have little influence on decision making. The best way to use their knowledge and skills is to make them part of a logistics team that manages the system design process.

A well-run distribution system should:

- Maintain a constant supply of medicines
- Keep medicines in good condition

- Minimize medicine losses caused by spoilage and expiry
- Rationalize pharmaceutical storage points
- Use available transport as efficiently as possible
- Reduce theft and fraud
- Provide information for forecasting medication needs
- Incorporate a quality assurance program

Designing/Redesigning distribution system

Distribution system design

Designing a new distribution system or, as is more likely in practice, evaluating and planning improvements to an existing system, requires systematic cost-effectiveness analysis and operational planning. Some guiding principles include:

- Managing and evaluating distribution and logistics as an integrated activity (for example, receipt, storage, distribution, and customer service operating together as a single system rather than as self-contained microsystems unconnected to one another)
- Ensuring distribution system operations are linked to the overall objectives of the medical stores and the broader public health system
- Ensuring customer service needs are understood and accommodated
- Balancing the trade-offs between costs and service (for example, although every hospital might like to have a medical store on its premises, the increases in inventory-holding and operating costs are unlikely to make such an option cost-effective)
- Keeping stock moving

- Minimizing lead times, inventory, and costs

- Analyzing ways to improve effectiveness (for example, reduce number of warehouses, contract out transport, invest in new information systems) as well as efficiency (for example, ensure full transport loads, minimize inventory, mechanize materials handling, automate order processing)

- Minimizing the steps in storage and handling, which decreases the opportunity for damage and loss

When the system is in place, regular performance monitoring is needed to ensure that the system functions as intended. The major design characteristics for a distribution network (see Figure 22 3) are considered in detail in subsequent chapters and are mentioned only briefly here.

Basic design features

The basic characteristics of a distribution system include its degree of centralization, the number of levels in the system, and the geographic or population coverage. Country Study 22-1 highlights the challenges of supplying tuberculosis (TB) medicines in the sparsely populated, mountainous country of Nepal. Comparable problems are faced by small island states, such as those in the Pacific, and geographically large countries with small, partially nomadic populations, such as Mongolia.

In a typical central supply model, pharmaceutical procurement and distribution are coordinated at the national level. Medicines received at the central medical stores (CMS) are distributed to lower-level warehouses and onward to the health facilities. In a decentralized system, the districts or regions are responsible for receiving, storing, and distributing medicines according to their needs; in some cases, they may also be responsible for procurement. Chapter 8 discusses various options for providing medicines to the public sector, some of which require in-house storage and some of which eliminate part or all of public-sector supply system warehousing. In designing a distribution system or redesigning an existing system, the following important steps have to be taken:

1. Determine the number of storage levels in the system

2. Determine the location of storage sites

3. Decide at which level of the supply system decisions will be made concerning orders

4. Fix resupply intervals or frequency of placing orders

5. Select a collection or delivery method for distributing medicines to user units

6. Select an appropriate mode of transport

7. Determine the amount of inventory to be held at each level in the system

8. Develop a set of feasible and economical delivery routes and work out a practical delivery schedule and appropriate modes of transport to service these routes; determine whether it is more efficient to keep and maintain vehicles or contract out the delivery service

9. Estimate the operating costs and assess the cost effectiveness of contracting for storage and transport at one or more levels

10. Establish a warehouse management system based on a set of standard operating procedures

Pharmaceutical transportation Management

Unreliable transport for pharmaceutical supplies is a major problem in many health care programs. Good transport practice demands reliability, efficiency, safety, accountability, timeliness, affordability, and sustainability. Transport is difficult to plan and manage well. Politicians and senior program managers generally assign greater priority to other, more visible, aspects of health care delivery. However, policy makers and administrators need to appreciate that effective and responsive health service depends on always having medicines available when and where they are needed, which requires the secure and proper transport of pharmaceuticals and medical supplies. If the pharmaceutical sector has to compete with other services for planned and emergency logistics, the consequences may be critical to public health.

Transportation network design

When designing a new transportation network or redesigning an existing one, answer the following questions:

1. What is the ideal distribution network, given current transport resources? Will it provide a satisfactory service level, without stock outs, at dispensing facilities?

2. What would be the ideal distribution network if more resources were available?

The points listed below are essential for any transportation network design, regardless of the size or complexity. By analyzing this information, you will be able to determine suitable transportation routes for delivery sequence and frequency to each facility. You can then use this information to identify the efforts and resources that could build an ideal distribution system.

These points include:

a. Monthly demand of products supplied to each health facility (total quantity, weight, and packaged volume): Location and distance of facilities from their supplying facility (national, regional, or district warehouse) by road, rail, air, or sea; project this information on maps for easily viewing, either on hard copy maps, or in electronic form using a geographic information system (GIS)

b. Fleet details: list of vehicles in use; their type; load capacity; and length of time, in days, the vehicles are available for health product delivery (in some cases, vehicles may not be solely for delivering health products)

c. Staff trained in activities related to transportation: proper equipment operation, safety, delivery schedule planning and execution, material handling, and reporting.

CHAPTER 7: WAREHOUSE AND INVENTORY MANAGEMENT

Objectives: After completing this chapter, students will be able to:

- Describe good storage practices
- Demonstrate cold chain storage management for cold chain products
- Define inventory management
- Define key terms in inventory control
- Describe importance good inventory management
- Describe purpose and types of inventory control system
- Apply ABC/VEN reconciliation and describe its application.

7.1. Pharmaceutical Warehouse Management

Products are stored at every facility in the pipeline; almost everyone working in the supply chain is responsible for product storage. Storage ensures the physical integrity and safety of products and their packaging, throughout the various storage facilities, until they are dispensed to clients. An important goal in storage of health products is the correct staging of health products to ensure that orders can be filled and distributed. Regardless of storage facility size; from a small health center to a central warehouse; the main operational activities for storage are very similar. How complex these activities become will vary based on the volume of products to be managed and storage facility size; as well as particular requirements, such as cold storage.

Storage and Product Shelf Life

Shelf life is the length of time a product may be stored without affecting the usability and safety of the item, if the product is stored under the prescribed conditions.

Pharmaceuticals have a shelf life which is specified by the manufacturer. When pharmaceuticals reach the end of their shelf, it has expired and should not be distributed to patients. Some health products have short shelf lives. Because of these short shelf lives, it is important that proper storage procedures are followed, so that the shelf life is protected.

Always check the expiry dates before receiving, issuing or using, and do not use products thathave expired. The expiry date of the products should be indicated directly on the product carton.

Most products have the expiration date already labeled on them. To find this important date lookin the following places:

i. On the carton in which the product is shipped

ii. On the inner box, packaging of the product

iii. On the product itself.

If the date is not on the outer carton look at the packaging. If it is not there, look at the product itself. In most situations, the expiration date will be found in one of the three locations mentioned above. Once the date is identified, write it in large numbers on the outer carton with a marker for easy identification.

If the expiration date is not available, look for the manufacture date on the carton, packaging, or product. By knowing the manufacture date and the shelf life of the product, one is able to determine the expiration date of the product. For example, if you receive an item with a manufacture date of February 2006, add the shelf life (for example, 18 months) to this date. The expiry date would then be August 2007. Once the expiration date is determined, write it in large numbers on the outer carton with a marker for easy identification. If you are unsure of the shelf life of a product, make an inquiry; then determine and write the expiration date once themanufacture date is known.

FEFO means ―first-to-expire, first-out‖. Always distribute products that will expire before other products. Do not follow ―first-in, first-out‖. To apply FEFO, Store Managers and Health Facility In-Charges should:

1. Write the expiry dates on the outside of cartons.
2. Place the cartons or products so that the first to expire are stacked in front of or on top of products that will expire later.
3. Distribute products from front to back or top to bottom so that products that expire soonerwill be issued first. Never distribute any product that will expire before it can be distributed to and used by the client

Storage guidelines

In general, supplies should be protected from sun, heat, and water. Follow manufacturer recommendations for storing supplies. This information is usually printed on the product carton and boxes. The following are general storage guidelines for pharmaceuticals

- ✓ Clean and disinfect storeroom regularly.
- ✓ Store supplies in a dry, well-lit, and well-ventilated storeroom, out of direct sunlight.
- ✓ Secure the storeroom from water penetration.
- ✓ Ensure that fire safety equipment is available and accessible, and that personnel aretrained to use it.
- ✓ Store latex products away from electric motors and fluorescent lights.
- ✓ Maintain cold storage, including a cold chain, for commodities that require it. – keepnarcotics and other controlled substances in a locked area.
- ✓ Store flammable products separately, using appropriate safety precautions.
- ✓ Stack cartons at least 10 cm (4 in) off the floor, 30 cm (1 ft) away from the walls andother stacks, and no more than 2.5 m (8 ft) high.
- ✓ Store medical supplies separately, away from insecticides, chemicals, old files, officesupplies, and other materials.
- ✓ Arrange cartons so that arrows point up; ensure that identification labels, expiry dates,and manufacturing dates are visible.
- ✓ Store supplies in a manner accessible for FEFO, counting, and general management.
- ✓ Separate and dispose of damaged or expired products without delay

Storage System

There are three types of commonly known storage systems. They are:

1. **Closed system**: all pharmaceuticals are physically stored in a closed or controlled area. The general practice is to maintain physical control by locking the storage area whenever there are no activities. As a rule, no one other than Stores personnel is permitted in the stores area. Materials enter and leave the area only with the accompaniment to an authorizing document. It is designed to afford maximum physical security and to ensure tight accounting controls of inventories.

2. **Open system:** usually applied in a situation when the widest use in highly repetitive, mass production types of operation exhibiting a continuous and predictable demand of the same materials. In plants using this system, no storeroom as such exists. Each

material is stored as close to its point of use as is physically possible. Materials are stored in bins, on shelves or racks, on pallets, into boxes, etc. However, the storage configuration (method of arrangement) at each workstation is arranged to fit the available space and storage facility.

Places less emphasis on the accounting control of materials. Materials are usually put into production without the use of requisition or a control document. No perpetual inventory records. To determine the actual usage of material during a given period, it is necessary to take a physical count of the material at the end of the period and to compare this figure with the similar beginning-period figures (which has been adjusted for materials receipts during the period). Hence, accounting changes are determined indirectly rather than directly.

3. **Random access storage system:** It is a unique type of closed stores system, employed by a relatively small number of large firms. In this system, no material has a fixed storage location (items stored in the first available bin or shelf suitable for its storage requirement). Items are located by a paper-work control system that utilizes punched card data processing equipment. The random-access storage system is clearly feasible only in large operation. It requires electronic data processing equipment, as well as an expensive control system. It has two important advantages if properly designed and operated:

First, it utilizes space much more efficiently than a fixed-location system. Second, the system provides great flexibility.

- ## Steps in pharmaceutical storage and key storage activities

Material receiving and incoming inspection: This activity occurs during the unloading of vehicles and includes the visual inspection of delivered packages to ensure that products were not damaged during transport. It is also important during this activity that you verify the quantities of products received against the packing slip or shipping invoice. Report any discrepancy.

Put away: This process includes moving products from the unloading dock, or receiving area, after they are released for storage; and assigning them to their designated storage area (rack, shelf, floor, etc.). It is important that every product moved into or out of the

racks, shelves, or any storage area is correctly recorded on the stock keeping records; an inventory control system

helps you manage them. Whether the process is manual or automated, the best practice is to put away products the same day they are received.

Picking and packing. To fill shipping requests (or picking lists), products must be located, pulled from inventory, and prepared for shipment. In some cases, products need to be packed into shipment containers or palletized; and, sometimes, bundled with other products into kits before being shipped. When any packing or repacking activity takes place, the new package mustbe labeled correctly.

Shipping: To guarantee good shipping accuracy, the list of products and their quantities must be checked against shipping orders, or requests, prior to preparing the required shipping documents and loading of the cargo for transport. To avoid damage during transit, products must bearranged and secured within the vehicle using the requirements and conditions for adequate loading and transport.

Irrespective of the location system, medicines must be stored within each zone in a way that would make them easily accessible to personnel while protecting their integrity. They can either be put on shelves (for small volume and weight), pallets, block-stacked pallets, and pallet racks. The storage room has designated areas for receiving, usable stock, and quarantine space. The quarantine space can be divided for unusable products to be disposed, and for products awaitinga quality control check. Major steps involved in pharmaceuticals storing are dejunking, logical organization and arrangement following ‒good pharmaceutical storage practices‖ and ‒overall pharmaceuticals management efficiency‖.

A. Conducting Visual Inspection

Visual inspection is the process of examining products and their packaging by eye to look for problems in product quality. To protect the quality of pharmaceuticals, it is important to conduct visual inspections of the products. A visual inspection should be completed each time products are handled: when receiving, issuing or dispensing supplies, or when conducting a physical count. When conducting a visual inspection, be sure to check the following:

a. **Package and product integrity:** check for damage to packaging (tears, perforations, water or oil) and products (unexpected odor, caking on bottles, change in color, broken bottles).

b. **Manufacturing defects:** incomplete supply, missing or illegible identification information.

c. **Labeling:** Make sure that products are labeled with the date of manufacture or expiration,lot number and manufacturer‘s name. For products coming in individual patient kit form like TB kit, check if the labeling includes Batch No and Expiry Date of each product within the Kit.

B. Dejunking and Organizing storage spaces

✓ Logical organization of pharmaceuticals in the store

✓ Organize the storage area into zones as needed: a cold storage area for vaccines and other supplies requiring cold storage; a secure room or locked cage for narcotics and controlledsubstances; a zone in which to store flammable materials, ideally in a separate building orroom.

✓ Organize pharmaceuticals on their shelves according to FEFO, first-to-expire, first-out. Put supplies that will expire sooner in front of or on top of pharmaceuticals that will expire later.

✓ Organize the storage area in an orderly manner so health supplies can be found easily andre-stocked easily.

✓ Designate a specific space for temporary storage of unusable items before their disposal.

- **Designing pharmaceutical warehouse**

During pharmaceutical store Layout and design

Develop a demand forecast.

✓ Determine each item‘s order quantity.

✓ Convert units into cubic footage requirements.

✓ Allow for growth.

✓ Allow for adequate aisle space for materials handling equipment.

✓ Provide for the transportation interface.

✓ Provide for order-picking space.

✓ Provide storage space.

✓ Provide recouping, office, and miscellaneous spaces.Warehouse Space

requirements

Five Main Areas of Warehouse Operation

i. Goods in (incoming of goods)

- ✓ Receipt- unload, temporary hold
- ✓ Check- correct goods received, grade, package, quantity, damage or shortage
- ✓ Record receipt and discrepancies
- ✓ Unpack, repack if necessary
- ✓ Decide goods location

ii. Main Store

- ✓ Locate goods in reserve storage area
- ✓ Confirm goods location to control function
- ✓ Issue goods to replenish order picking stock

iii. Order Picking: forward store

- ✓ Select goods for customer orders
- ✓ Pack and check
- ✓ packaging material store

iv. Marshalling

- ✓ Assemble goods by customer or by vehicle load

v. Goods out: outgoing goods

- ✓ Loading facilities for vehicles
- ✓ Vehicle dispatch schedules

Meaning of Warehouse Layout and its Relation to Pharmaceuticals/ Materials Flow

The layout is the framework in which the overall storage space arrangement is developed. The complete floor plan shows the actual manner in which the gross space with in the storage area is used. The plan shows the division of the space to the storage, receiving, shipping areas, main aisles, crosses aisles, fire aisles, and offices. It enables planning for the effective use of space. It enables quick response-essential to economic warehouse operations.

Principles of Stores Layout Plan

Item similarity: e.g., similar handling requirements stored together

Item popularity: fastest moving bulk stocks should be stored in areas that allow quick and easy access to reduce travel of materials handling equipment and Stock Selection

personnel. Fast- moving Bin stocks should be easily accessible to expedite stock selection and replenishment

actions. Items with the lowest turnover rate should be planned for placement in areas progressively farther away from active stock or processing areas.

Item size/Dimension and weight: the dimensions and weight of individual items affect not onlythe amount of storage space allotted, but also the location in which items are to be stored.

Item's quantity: it is frequently desirable to increase the amount of space assigned to an item ina single location in order to eliminate the need for other locations.

Item characteristics: most items do not require special storage areas. Some items do require: **Hazardous items:** needs to be specially stored or handled to prevent a hazard to personnel andfacilities.

Sensitive material: requires a high degree of protection and control due to statutory requirements or regulations,(e.g., narcotics and drug items; precious metals, items which are of high value; highly technical).

Perishable and deteriorative: some materials have limited storage life and care must be takento assure that the oldest stock or that which may have an earlier expiration date is issued first.

Importance of Layout Planning

The most critical factor in warehousing is space. How an organization organizes and uses space has a profound effect on the efficiency of the personnel and their ability to improve service delivery for their customers.

Layout planning is the discipline of assessing the space requirements of a warehouse or other storage facility and specifying how that space should be organized to facilitate identifiable warehouse activities. The main objectives of layout planning are to:

- ✓ Use space efficiently.
- ✓ Promote the efficient handling of commodities.
- ✓ Provide economical storage.
- ✓ Provide flexibility to meet changing warehousing requirements

Aisles: preplanning of aisle positioning or layouts must be done prior to placement of materials.

- ✓ Allowing the aisle layout to take shape as materials are placed in stock may result inplacing materials in inaccessible locations & loss of space.

- ✓ Aisles should be wide enough to provide maneuvering room for the materials handlingequipment available for the stock storage and selection actions.

- ✓ Width of aisles between Bin and Shelving areas should permits easy movements of stock operator/ selector trucks.
- ✓ Aisles should be planned to provide straight and clear passageways.

Principles of safety: properly designed layout provides a sufficient space for the pedestrians or stores persons or equipment. Moreover, store items must not concentrate in one area.

Principles of continuous flow: processing time and costs are minimized - allow direct flow

Principles of economy of operation: the greatest material handling economy is achievedin the warehouse when materials are:

- ✓ moved in straight or direct lines
- ✓ moved through a minimum of distance
- ✓ moved by mechanical means

The principles of flexibility: shall be designed by anticipating the need for future expansions. Maximize the use of labour, space and equipment.

When considering the layout and operation of any warehouse system, there are fundamental principles that embody a general philosophy of good practice. These are:

- ✓ Use the most suitable unit load
- ✓ Making the best use of space
- ✓ Minimizing movement
- ✓ Controlling movement and location
- ✓ Providing safe, secure and environmentally sound conditions
- ✓ Maintaining at minimum overall operating costs

Three broadly classified layout plans:

1. The straight-through flow: is the simplest form

- ✓ In one end; out the other
- ✓ Progressive movement of materials
- ✓ Clean layout
- ✓ Easy to schedule and control
- ✓ Easy expansion

- ✓ Suited to long products or long process machining with column spacing to supporttraveling bridge cranes or conveyors.

2. U-shaped flow

- ✓ Materials return to starting point
- ✓ Only one roadway for transport in and out
- ✓ Combined receiving and shipping with savings in doors, supervisors, office space,handling crew, etc
- ✓ Raw and finishing storage adjacent, balancing storage space & workforce
- ✓ Mobile handling equipment routed in sequence of flow with increased utilization
- ✓ Tends to be compact with minimum exterior wall cost
- ✓ Energy savings from less exterior surface & fewer openings

3. L-shaped flow

- ✓ In one side and out one end
- ✓ Less interference between different modes of transportation
- ✓ Different types of operation, storage or service areas are easier to segregate
- ✓ Easier to split inflow and outflow of physically different raw materials, products andsupplies
- ✓ Well suited for manufactured products with high proportion of purchased parts storedclose to assembly
- ✓ Can get heavy utility areas in corner with less costly expansion to the outside

Pharmaceutical Disposal

Pharmaceutical waste means wastes which encompass the following:

- ✓ All properly unsealed bulk products or loose tablets and capsules. If unexpired theseshall only be used when the container is still sealed, properly labeled or still within the original unbroken blister packs,
- ✓ All cold chain damaged, unexpired medicines that should have been stored in a coldchain but were not,
- ✓ Counterfeit, substandard and adulterated,
- ✓ Discarded items used in the handling of medicines,
- ✓ Expired, unused, spilt, and contaminated,

- ✓ Improperly sealed or labeled or stored,
- ✓ Expired, damaged, and improperly sealed or labeled or stored laboratory reagents,
- ✓ Expired, damaged, and improperly sealed or stored medical supplies;
- ✓ Prohibited or unauthorized medicines,
- ✓ Expired, damaged, and improperly sealed or labeled or stored raw materials, and
- ✓ Discarded packing materials.

A well-functioning logistics system is fundamental to the proper management of pharmaceutical wastes at various levels in the logistics system, including adequate storage, handling, and transport from the originating facility to the final disposal.

Pharmaceutical waste storage and handling

To store pharmaceutical wastes properly and safely, it is recommended to follow any existing standard operational procedures (SOPs). Store chemical wastes, such as expired pharmaceuticals separately from unexpired product. When possible, separating pharmaceutical wastes where it isgenerated, based on the main categories is important:

- ✓ Infectious hazardous
- ✓ Non-hazardous waste
- ✓ Non-infectious but hazardous
- ✓ General waste.

Hazardous waste must be contained and separated from general waste. Individual facilities could also send the waste to the central level instead of running their own disposal. This type of reverse logistics could consolidate pharmaceutical wastes from various facilities and, potentially, lower costs related to waste disposal. The disposal of pharmaceutical wastes uses different methods, depending on the type of waste to be treated. Some disposal requires autoclaving, others incineration. Waste or its residue can be buried in a protected pit or sent to a landfill for disposal.

Procedures for handling medical wastes

- ✓ Check the presence of unfit for use medical products such as expired, damaged, returned products by looking on bin cards or other stock controlling mechanisms such as electronic data base and confirm the stock present in the warehouse. Investigate when there is discrepancy.
- ✓ Separate unfit for use medicines from useable stocks including expired, damaged and returned products in to designated quarantine room.
- ✓ Record each medicine waste on the register book and compile appropriately, made ready for regulatory inspection.
- ✓ Establish a disposal team consisting of supervising pharmacists, store house keepers, whoare experienced pharmaceutical warehouse personnel.
- ✓ Sorting out of each pharmaceutical from stockpiles into separate categories for which different disposal methods are required. Sorting is done in the open or in a well-ventilatedarea as close as possible to the stockpile in an orderly way, with all sorted materialclearly labeled and separated at all times.

- ✓ Supply staffs with protective equipment (gown, gloves, boots, dust masks, etc.), and works under the direct supervision of a pharmacist.
- ✓ Train disposal team on sorting criteria, and health and safety risks associated withhandling wastes.
- ✓ The first step in dealing with stockpiles is to remove and dispose of non-drug, non- chemical items. All such items should be clearly separated from pharmaceuticals and chemicals.
- ✓ For those to be disposed a decision is made on the best method of disposal. The pharmaceuticals to be disposed should be separated from their packaging at disposal site.
- ✓ The remaining unwanted pharmaceuticals that should never be used and consideredpharmaceutical waste must be:

a. Sorted by active ingredients

- ✓ Controlled substances; e.g. narcotics, psychotropic substances
- ✓ Anti-infective drugs
- ✓ Antineoplastic
- ✓ Antiseptics and disinfectants etc.

b. Sorted by dosage form:

- ✓ Solids, semi-solids and powders such as tablets, capsules, granules, powders forinjection, mixtures, creams, lotions, gels, suppositories, etc.;
- ✓ Liquids such as solutions, suspensions, syrups, etc.; and ampoules;
- ✓ Aerosol canisters such as propellant driven sprays and inhalers.
- ✓ Once sorted, the pharmaceuticals wastes should be carefully packed into steel drums or into containers such as sturdy cardboard boxes, with the contents clearly indicated on the outside of the containers.
- ✓ Label containers containing sorted medicines waste and kept in a dry, secure and preferably aseparate room.

- ✓ Submit recorded medicine waste along with application letter and communicate withappropriate regulatory body ahead of disposal date.
- ✓ Disposal site is selected in agreement with appropriate regulatory body consideringEnvironmental Impact Assessment
- ✓ Transporting of sorted medicines waste to agreed disposal sites in closed motor vehicles toavoid pilferage.
- ✓ Dispose sorted medicines with appropriate disposal method in the presence of EFMHACAinspectors as per national disposal legislatives.
- ❖ Formal request of Disposal Certificate from the Authority and document disposal certificatefor regulatory purpose and show to inspectors when requested.

Pharmaceutical disposal methods

1. Landfill

To landfill means to place waste directly into a land disposal site without prior treatment or preparation. Landfill is the oldest and the most widely practiced method of disposing of solid waste. Three types are recognized.

1.1. Open uncontrolled non-engineered dump

A non-engineered dump is probably the most common land disposal method in developing countries. Untreated waste discharged into an uncontrolled, no engineered open dump does not protect the local environment and should not be used. Discarding of untreated waste pharmaceuticals into such a site is not recommended except as a last resort. They should preferably be discharged after immobilization by encapsulation or inertization. It should be noted that discarding in open, uncontrolled dumps with insufficient isolation from the aquiferor other watercourses can lead to pollution, with the risk of drinking water contamination in the worst cases.

1.2. Engineered landfill

Such a landfill has some features to protect from loss of chemicals into the aquifer. Direct deposit of pharmaceuticals is second best to discharging immobilized pharmaceutical waste into such a landfill.

1.3. Highly engineered sanitary landfill

Properly constructed and operated landfill sites offer a relatively safe disposal route for municipal solid wastes, including waste pharmaceuticals. The top priority is protection

aquifer. An appropriate landfill consists of an evacuated pit isolated from watercourses and above the water table. Each day‘s solid waste is compacted and covered with soil to maintainsanitary conditions. The term ―safe sanitary landfill‖ refers to such a site that is adequately situated, constructed and managed.

2. Waste immobilization: encapsulation

Encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. Drums should be cleaned prior to use and should not have contained explosive or hazardous materials previously. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand.

3. Waste immobilization: Inertization

Inertization is a variant of encapsulation and involves removing the packaging materials, paper, cardboard and plastic, from the pharmaceuticals. Pills need to be removed from their blister packs. The pharmaceuticals are then ground and a mix of water, cement and lime added to form a homogenous paste. Worker protection in the form of protective clothing and masks is required as there may be a dust hazard. The paste is then transported in the liquid state by concrete mixer truck to a landfill and decanted into the normal urban waste. The paste then sets as a solid mass dispersed within the municipal solid waste. The approximate ratios by weight used are as follows:

- ✓ Pharmaceutical waste: 65%
- ✓ Lime: 15%
- ✓ Cement: 15%
- ✓ Water: 5% or more to form a proper liquid consistency.

4. Sewer

Some liquid pharmaceuticals, e.g. syrups and intravenous (IV) fluids, can be diluted with water and flushed into the sewers in small quantities over a period of time without serious public health or environmental affect. Fast flowing watercourses may likewise be used to flush small quantities of well-diluted liquid pharmaceuticals or antiseptics.

5. Burning in open containers

Pharmaceuticals should not be destroyed by burning at low temperature in open containers,as toxic pollutants may be released into the air. Paper and cardboard of the

packaging, if they are not to be recycled, may be burnt. Polyvinyl chloride (PVC) plastic however must not be burnt. While burning pharmaceutical waste is not advocated as a method of disposal, it is recognized that it is not infrequently used. It is strongly recommended that only very small quantities of waste pharmaceuticals be disposed of in this way.

6. Medium temperature incineration

In many countries there are no high temperature, two–chamber incinerators designed to handle more than 1% halogenated compounds. Such incinerators meet strict emission control standards, such as those published by the European Union. However, it is likely that only medium temperature furnaces and incinerators will be available. Responsible authorities mayconsider it acceptable to treat expired solid form pharmaceuticals using a two–chamber incinerator that operates at the minimum temperature of 850°C, with a combustion retention time of at least two seconds in the second chamber.

7. High temperature incineration using existing industrial plants

High temperature incineration using existing industrial plants Industries which use high temperature technology, such as cement kilns, coal fired thermal power stations or foundries, usually have furnaces that operate at temperatures well in excess of 850°C, have longcombustion retention times and disperse exhaust gases via tall chimneys, often to highaltitudes. Many countries do not possess and cannot justify economically, expensive and sophisticated chemical waste disposal facilities, so the use of an industrial plant provides a viable and cheap alternative. Cement kilns are particularly suited for the disposal of expired pharmaceuticals, chemical waste, used oil, tyres, etc. Several features of cement kilns make them suitable for pharmaceutical disposal. During burning the cement raw materials reach temperatures of 1450°C, while the combustion gases reach temperatures up to 2000°C.

8. Chemical decomposition

If an appropriate incinerator is not available, the option of chemical decomposition can be used in accordance with the manufacturer's recommendations, followed by landfill. This method is not recommended unless chemical expertise is readily available. Chemical inactivation is tedious and time consuming, and stocks of the chemicals used in

treatment must be made available at all times. For disposal of a small quantity of antineoplastic drugs this method may be practical. However for large quantities, for example, more than 50 kg of anti-neoplastics, chemical decomposition is not practical, as even small consignments need tobe treated through repeated application of this method.

Summary of pharmaceutical categories and disposal methods

Category	Disposal methods	Comments
Solids	Landfill	No more than 1% of the daily municipal waste should be disposed of daily in an untreated form (non-immobilized) to a landfill.
Semisolids	Waste encapsulation	
Powder	Waste inertization Medium and high temperature incineration (cement kiln incinerator)	
Liquid	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics not to sewer
Ampoules	Crush ampoules and flush diluted fluid to Sewer	Antineoplastics not to sewer.
Anti-infective drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to a sewer.
Antineoplastics	Return to donor or manufacturer Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator) (chemical decomposition)	Not to landfill unless encapsulated. Not to sewer. No medium temperature incineration.
Controlled drugs	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Not to landfill unless encapsulated.
Aerosol canisters	Landfill Waste encapsulation	Not to be burnt: may explode
Disinfectants	Use To sewer or fast–flowing watercourse: small quantities of diluted disinfectants (max. 50 litres per day under supervision)	No undiluted disinfectants to sewers or water courses. Maximum 50 litres per day diluted to sewer or fast–flowing watercourse. No disinfectants at all to slow moving or stagnant watercourses
PVC plastic, glass	Landfill	Not for burning in open containers.
Paper, cardboard	Recycle, burn, landfill	

- ## Cold chain Management

Vaccine Storage Requirement

The presentation and formulation of vaccines determines the storage requirement, maximum storage time at primary and sub national level, type of cold chain equipment used during storage and transportation at all levels of the vaccine supply chain system. In Ethiopia there are vaccine which required two different temperature rage storage requirements at central and EPSA hub level. A negative storage temperature is required (-25 ^{0}C to -15^{0}C) to store OPV vaccines, and currently ultra-cold chain (-80°C to -60 °C in freezer) is required for some of the COVID 19 vaccine such as Pfizer. A positive temperature required (2 °C to 8^{0}C) for the rest of the vaccines at all supply chain level. BCG and measles can be stored at (-25 ^{0}C to -15^{0}C) at central and ESPA hub level if there is adequate negative storage capacity. The maximum recommended storage period at Central and EPSA hub level is six and three months respectively. All vaccines and diluents in woreda and health facilities should be store in a temperature range of 2 ^{0}Cto 8^{0}C for a maximum of one month period.

Cold Chain Capacity

Cold chain is the backbone of a vaccine supply chain system. The cold chain capacity at all level should be evaluated yearly for basic replacement and expansion plan in line with the demand of the immunization program. During forecasting exercise cold chain storage capacity should be considered to minimize vaccine wastage rate due to overstocking of vaccines.

Vaccine stock on hand

It is the quantities of usable stock available in the system. It does not include damaged, expired, and VVM stage at discard point. The amount of stock on hand should be calculated before ordering new stock to avoid having too much vaccine delivered with no place to store it or storing vaccine for too long at the most peripheral level where the cold chain is weakest.

Vaccine utilization and wastage

Vaccine utilization and wastage is another factor in forecasting vaccine needs. Vaccine utilization is the proportion of vaccine that is supplied and administered. Vaccine wastage is the proportion of

Vaccine Usage Rate =	Children vaccinated (Dose used) / (Beginning Balance +Received During the Month) - End Balance	X 100
Vaccine wastage = 100 – Vaccine usage rate		

Some wastage is predictable and acceptable. For example, most health workers do not get all of the doses out of a multi-dose vial, and managers should plan accordingly. However, wastage rates higher than expected can be an indicator of operational problems in a health facility.

High wastage can also indicate problems in cold chain or vaccine stock management if vaccine must be discarded because of breaks in the cold chain or expiration of vaccines. At the same time, high wastage may be an unavoidable consequence of policies to provide services to sparsely settled populations. Managers need to interpret findings of excessive wastage carefully before taking actions that result in lower immunization coverage.

Reserve requirements

Reserve stock is the additional amount of vaccine needed in case of an emergency, such as a sudden increase in demand, higher than expected wastage, or delays in re-supply. Most programs maintain a reserve stock of 25% over the amount they expect to use during the supply period, but experience should dictate this proportion.

How to pack a vaccine carrier

1. Confirm that there are no cracks in the walls of the vaccine carrier.
2. Make sure that the vaccine carrier is cool to prevent early melting
3. Take out the required number of ice packs from the deep freezer and wipe them dry. Keep them out side for conditioning before placing into carrier.
4. Place four numbers conditioned ice packs in the carrier and wait for few minutes for temperature to fall to less than 8 degree Celsius in the carrier. Never use only two conditioned ice pack/ cool water pack for vaccine carrier.
    - ✓ Place foam pad at the top of ice packs.
    - ✓ Ensure that some ice is present in the ice packs while conducting immunization sessions.
    - ✓ Secure the lid tightly

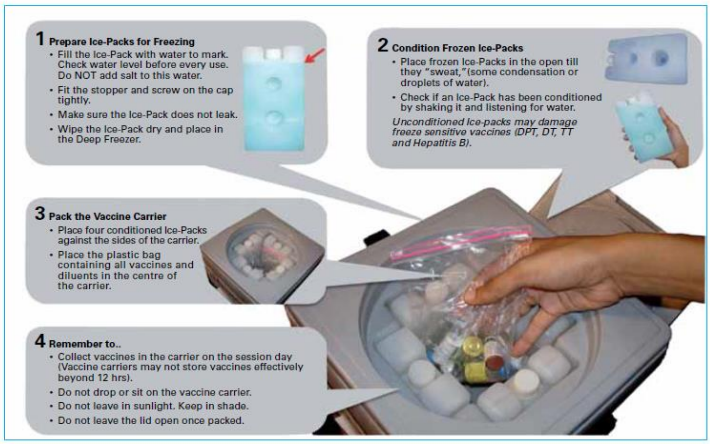
1 Prepare Ice-Packs for Freezing
• Fill the Ice-Pack with water to mark. Check water level before every use. Do NOT add salt to this water.
• Fit the stopper and screw on the cap tightly.
• Make sure the Ice-Pack does not leak.
• Wipe the Ice-Pack dry and place in the Deep Freezer.
2 Condition Frozen Ice-Packs
• Place frozen Ice-Packs in the open till they "sweat," (some condensation or droplets of water).
• Check if an Ice-Pack has been conditioned by shaking it and listening for water.
Unconditioned Ice-packs may damage freeze sensitive vaccines (DPT, DT, TT and Hepatitis B).
3 Pack the Vaccine Carrier
• Place four conditioned Ice-Packs against the sides of the carrier.
• Place the plastic bag containing all vaccines and diluents in the centre of the carrier.
4 Remember to..
• Collect vaccines in the carrier on the session day (Vaccine carriers may not store vaccines effectively beyond 12 hrs).
• Do not drop or sit on the vaccine carrier.
• Do not leave in sunlight. Keep in shade.
• Do not leave the lid open once packed.

Figure: Packing vaccine carrier

Collect vaccines in the carrier on the session day (Vaccine carriers may not store vaccines effectively beyond 12 hrs).

- ✓ Do not drop or sit on the vaccine carrier.
- ✓ Do not leave the vaccine carrier in sunlight. Keep it in shade.
- ✓ Do not leave the lid open once packed.

If more than one vaccine carrier is being carried, keep the whole range of the vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

Monitoring temperature exposure during vaccine transport

The aim of vaccine distribution management is to ensure that vaccines are transported within the correct temperature range in order to eliminate vaccine losses due to freezing and/or excessive heat exposure. Records must be kept to ensure that this policy is being achieved.

- ✓ Where freeze-sensitive vaccine is transported in cold boxes or vaccine carriers, at least one freeze indicator must accompany every delivery.
- ✓ Freeze indicators are not required in cold boxes, packed with fully frozen or conditioned icepacks, when these are used to transport OPV and lyophilized vaccines that are not damaged by freezing.
- ✓ Refrigerated vehicles, used for transporting vaccine, must be equipped with cab-mounted continuous temperature recording equipment and alarm systems. In addition, at least one freeze indicator device must also accompany every shipment.
- ✓ The freeze indicator device(s) should be placed with the most freeze-sensitive vaccine in the shipment at the time when the vaccine is packed in the issuing store.

The status of the freeze indicator(s) and of the Vaccine Vial Monitors (VVMs) must be checked at the time of arrival in the receiving store and details must be recorded on the Requisition and Issue Voucher form. Where refrigerated vehicles are used, temperature alarm events must be reported to the receiving store(s) so that additional checks of the vaccines can be carried out.

Freeze indicators should be placed with the most freeze-sensitive vaccine in each shipment. Typically this will be either the HepB or the pentavalent DTP-HepB-Hib or DTP-HepB+Hib vaccine. Freeze indicators DO NOT need to be placed in cold boxes which only contain BCG, OPV, Measles, MR or MMR because these vaccines are not damaged by freezing.

- ## Introduction to inventory management

Inventory management refers to the process of ordering, storing, using, and selling of pharmaceuticals. It is approach for keeping track of the flow of inventory.

Inventory management is the heart of the pharmaceutical supply system; in fact, the non-specialist might say that inventory management is pharmaceutical management. That would be simplistic, as the other chapters of this book demonstrate, but without a healthy inventory management system, the pharmaceutical supply system as a whole will not be viable.

Inventory management for pharmaceutical supply sounds easy; all that must be done is to order, receive, store, issue, and then reorder a limited list of items. In reality, the task is difficult, and in many countries, poor inventory management in the public pharmaceutical supply system leads to waste of financial resources, shortages of some essential medicines or overages of others resulting in expiration, and decline in the quality of patient care.

The objective of good inventory management is to maintain steady supply to operating units (and patients) while minimizing the costs of holding inventory and managing inventory. Compiling information on the total variable costs of inventory management (drug acquisition costs, inventory holding costs, purchasing operations costs, and shortage costs) allows managers to evaluate strategies for reducing costs.

–Sick‖ inventory management systems generally feature subjective, ad hoc decisions about order frequency and quantity, inaccurate stock records, and a lack of systematic performance monitoring. These problems are directly related to lack of knowledge and appreciation of what inventory management means as well as to ineffective management.

In many cases no systematic procedures and rules exist to guide staff, a problem compounded by lack of understanding of the basic issues of proper inventory management on the part of managers. Seven basic issues mustbe carefully considered when an inventory management system is being initially designed or upgraded:

- ✓ Definition of the context in which the inventory management system must function
- ✓ Determination of the types of stock records and inventory reports needed
- ✓ Selection of items to be stocked as standard items
- ✓ Maintenance of appropriate service levels for different classes of items
- ✓ Adoption of a decision rule or a model for determining when to reorder
- ✓ Adoption of a decision rule or a model for determining how much to reorder
- ✓ Identification and control of inventory management costs using product classification systems such as ABC analysis, VEN analysis, level of use, and other cost minimizing techniques.

A vehicle fuel gauge is a good representative example of an inventory control system.

Figure 1 fuel gauge

While driving, you monitor your fuel consumption from time to time and decide when to purchase more gas. By assessing the supply status of the tank, you can calculate when to refuel and how much, depending on your destination and your budget. Drivers often use the red warning area as an indicator of when to buy more fuel. Drivers replenish the tank on a specific day of the week, regardless of the level, adding enough fuel to reach full. In

deciding on an approach, drivers are choosing a form of inventory control.

- **Purpose of Inventory Control System:**

The purpose of an inventory control system is to inform the store man or other concerned body when and how much of a pharmaceutical to order/issue and to maintain an appropriate stock level to meet the needs of patients. Effective inventory control results in minimization of wastage and stock out while it increases availability of pharmaceuticals at any time.

8.1. Terminologies of Inventory Control System

1. **Maximum months of stock:** is the largest amount of each pharmaceutical a facility should hold in the store at any one time. If a facility has more than the maximum for a commodity, itis over stocked'and risks having commodities expire before they are used.
2. **Minimum months of stock:** is the approximate level of the stock on hand at the time of theexpected arrival of the next delivery from the supplier.
3. **Emergency order point**: is the level where the risk of stocking out is likely, but there is still time to receive an emergency delivery to avoid stock-out. It can be reached at any point during the review period. The EOP must be lower than the min.
4. **Max-min inventory control system:** A max-min inventory control system is designed to ensure that the quantities in stock fall within an established range.

5. **Review period/review period stock:** This is the routine interval of time between assessments of stock levels to determine if additional stock is needed**.** This term is also called the order interval or resupply interval, but review period is preferred because in some max- min systems, a review does not always result in an order being placed. Review period stockis the quantity of stock dispensed during the review period.
6. **Safety stock level:** This is the additional buffer, cushion, or reserve stock kept on hand to protect against stock outs caused by delayed deliveries, markedly increased demand, or other unexpected events. The safety stock is expressed in number of months of supply, which can also be converted into a quantity.
7. **Lead time stock level:** This is the level of stock used between the time new stock is ordered and when it is received and available for use. The lead time stock

level is expressed in number of months of supply, or as a quantity.

8.2 Types of Inventory Control System

Based on the time of setting order/making issue, there are three types of inventory control systems. These are:

1. Forced-ordering system: the trigger for ordering is the end of the review period.
2. Continuous review system: the trigger for ordering is when the facility reaches the minimum level.
3. Standard system: the trigger for ordering is the end of the review period for the commodities that are at the minimum level.

8.2.1 Forced-ordering system

The forced-ordering max-min system action is done at the end of each and every review period—either a requisition is made by the facility, or a facility sends a report with data to help their supply source to determine how much to allocate to that facility.

- **Forced ordering max-min system storekeeper decision rule**

In a forced-ordering max-min system, storekeepers do not use the min, because they always take action at the end of the review period. The review period, then, is the trigger for ordering.

At the end of each review period, review all stock levels and order or issue enough stock to bring the levels up to the max. Place an emergency order if the stock level for any item

Storekeepers must be careful not to run out of stock. Therefore, in addition to applying the decision rule for ordering, they are given an EOP. Storekeepers will know that they have reachedthe EOP if they frequently assess stock.

One variation of a forced-ordering max-min system is the delivery truck system, sometimes called a topping up or bread truck system. It can also be called Vendor Managed Inventory (VMI) system. In a delivery truck system, a truck is loaded with supplies at the end of the review period. The truck and a delivery team travel to each facility, assess the stock, and leave (top up) an amount of each product that is sufficient to bring stock levels up to the max at that location.

Advantages of forced ordering max-min system

- The storekeeper‘s decision rule is simple: order/issue every item at the end of

the period.

- Because orders are placed at regular intervals (i.e., the end of each review period), transportation can be scheduled for specific times, making it easier to ensure the availability of transport resources.
- Every facility orders or is resupplied at the end of every review period.
- Because all items are ordered/issued at the end of every review period, storekeepers do not need to constantly assess stock status, unless they think a potential stock out is possible.

Disadvantage of a forced-ordering system

- Orders for some items may be for small quantities; because all items are ordered,regardless of the stock on hand.

8.2.2 Continuous review system

Continuous review max-min inventory control is probably the least appropriate for most healthprograms; but when it is appropriate, it can be very effective.

Continuous review max-min system storekeeper decision rule

Review the stock level of each item every time you make an issue. If the stock level is at the min,or has fallen below the min, order enough stock to bring the level up to the max.

In a continuous review system:

- ✓ The review period is not fixed; a decision about whether to order is made each time aproduct is issued.
- ✓ The storekeeper must know both the max and min stock levels.

falls below the emergency order point before the end of the review period.

- ✓ The storekeeper does not need an emergency order point, because an order can be placed any time stock is needed.
- ✓ The storekeeper must assess stock status each time an issue is made. In a system with many items, this means that the storekeeper‘s workload increases; in a forced-ordering system, the storekeeper needs to assess stock status only when levels appear low enough to warrant an emergency order.
- ✓ The storekeeper must be able to order (pull) stock from the higher level, because the storekeeper is the only one who can determine whether the min stock

level has been reached. A continuous review system must be a pull system.

One variation of continuous review max-min systems is the two bin system. In the two bin system, the storekeeper has two equal-sized bins (containers, boxes, cartons, sacks, or other receptacles) of each individual product (i.e., not a kit of products). When the first bin is empty, the min has been reached. An order is placed for another bin (i.e., a bin‘s worth of stock), and thestorekeeper begins issuing from the remaining bin. The arrival of a new bin brings the stock levelup to the max.

Advantages of continuous review system

- The storekeeper‘s decision rule is simple.
- The system is more responsive and flexible because orders can be placed at any time.
- Small orders are eliminated because stock levels are at the min when an order is placed.

Disadvantages of a continuous review system

- Transportation resources are harder to schedule because orders can be placed at any time; a single facility can order pills one day, condoms the next, and HIV test kits the following week.
- In facilities with a large number of products, or a great deal of activity, the storekeeper‘s job is harder because the stock status must be assessed every time stock is issued.

8.2.3 Standard system

Theoretically, the standard version of the max-min system is the most effective because it combines the decision rules of both forced-ordering and continuous review and, therefore, sharesthe advantages of both. However, it also has disadvantages.

In a standard system:

- When to make an order or issue new stock is based on the min stock level and thereview period. This means that the storekeeper must know the min, max, and review period.
- The storekeeper will need an emergency order point to ensure that a stock out does not occur between review periods.
- The storekeeper must assess the stock status at the end of each review period and at any time levels appear to be low enough to warrant an emergency order.

Advantages of standard system

- ✓ Small orders are eliminated because an order is placed only when stock levels are at or below the min.
- ✓ In programs with many products, standard systems eliminate the need to assess stock status continually (as in continuous review) and to reduce the number of calculations that must be made because fewer products will be ordered or issued than in forced-ordering.
- ✓ Because orders are placed at regular intervals (i.e., at the end of each review period), transportation can be scheduled for specific times, making it easier to ensure the availability of transport resources.

Disadvantages of standard system

- ✓ The primary disadvantage of a standard system is that the min stock level is higher, increasing the likelihood of expiry and requiring more storage capacity, both of which mean increased costs.
- ✓ Storekeepers must learn the max, min, and EOP; know how to assess stock status; and be able to calculate the order or issue quantity. More training for the storekeepers may be required because their decision rules are more complex.

8.3 Reporting and Ordering of Pharmaceuticals

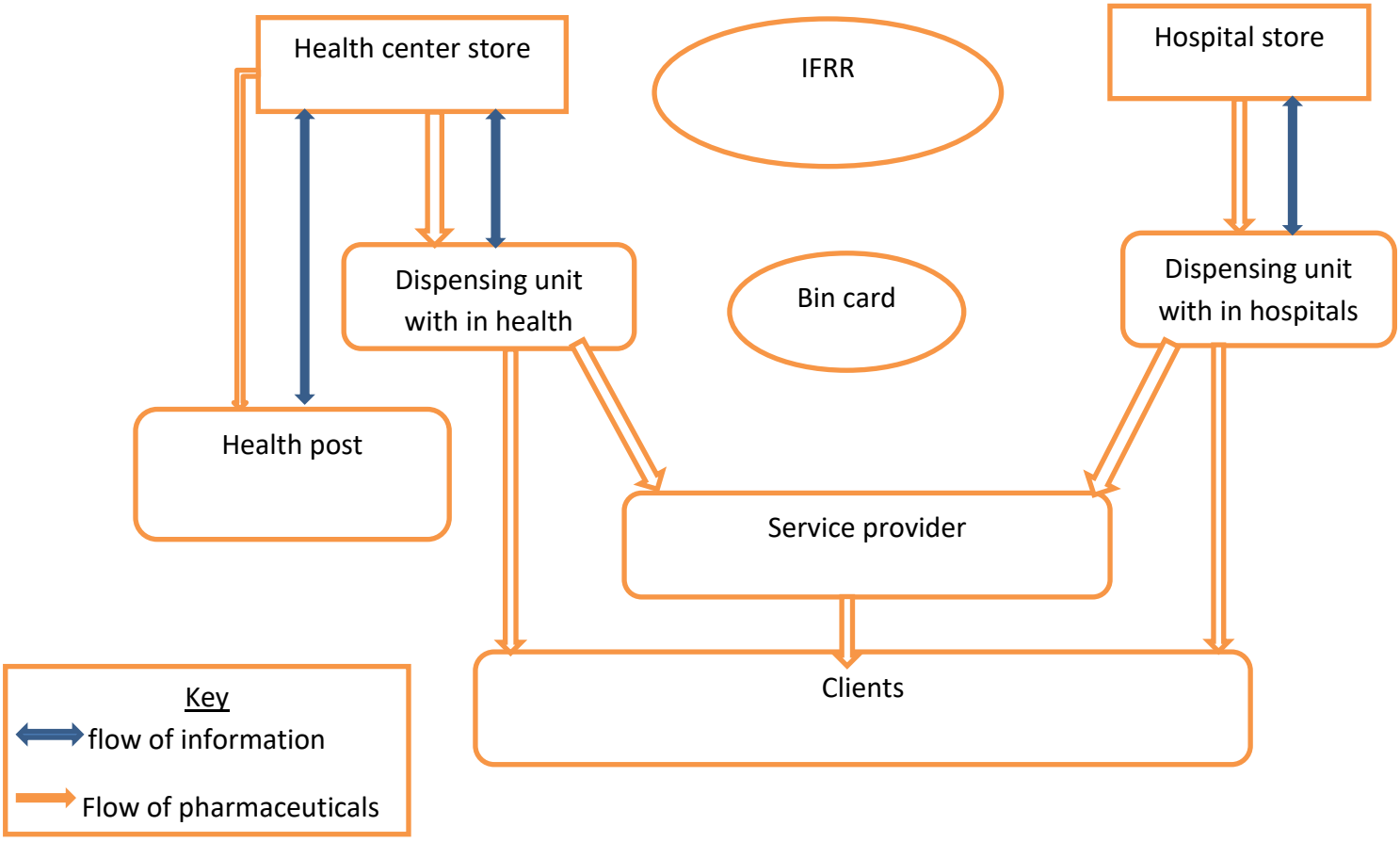

Figure 2 Movements of Products and Information between Health Centre and Health Posts and between Facilities and Internal Dispensing Units

- **VEN and ABC Analysis Pharmaceutical**

A. VEN Analysis

VEN is a system of categorization of medicines based on their degree of importance to provide appropriate services at health facilities. It is a method of classifying medicines by their clinical importance into Vital (V), essential (E) or nonessential/less essential (N).

For the VEN analysis to takes place, facility specific medicines list should be available and the categorization should be done by the health facility‘s Drug and Therapeutics Committee (DTC) as part of the medicines list preparation process.

The criteria for prioritization of medicines into VEN are as follows:

Vital (V)

Vital medicines are very essential medicines that are:

1. Potentially lifesaving, without which it is impossible to save patients life /patient may dieor may be harmed or disabled due to lack of this medicine.
2. Crucial to provide basic health services, without which it is impossible to deliver thebasic services in the specific catchment area (in its absence service may be discontinued).
3. It is mandatory to be available 24 hours of a day, 7 days of a week, and twelve months ofa year.

Essential (E)

Essential medicines are those that are:

- ✓ Effective against less severe but significant illness, not vital; it is between Vital and lessessential.
- ✓ Important to provide basic health services without which patients may be indifficulty/problem may be somehow substituted.
- ✓ Essential to the service without which it is difficult to give the health service.
- ✓ It is mandatory at least once a day, or at least once in a week, or at least once in a monthor once in a quarter of the year, but not as highly mandatory as vitals.

Nonessential (N)

Non-essential medicines are less essential medicines that are:

- ✓ Effective for minor illnesses and have low therapeutic advantage
- ✓ Important to patients; however, patients will not die due to the absence of thesemedicines
- ✓ Necessary to give the health service ; however , health service delivery will not bediscontinued in the absence of these medicines

Last priority medicines (In situations of budget limitation, these categories are the first tobe adjusted in reconciling requirements with the budget/fund)

The following table presents various patient and medicine-related criteria used to classify medicines by VEN.

Characteristic of Drug or Target Condition	(V)Vital, Crucial	(E) Essential	(N) Non-Essential or Less Essential
Persons affected (% of population) in case of	Over 5%	1-5%	Less than 1%
drugs used for disease of infrequent prevalence but may cause severe infections.			
Persons treated (number of patients per year at an average level of health facility) in case of drugs used for disease of infrequent prevalence but may cause severe infections.	Over 5%	1-5%	Less than 1%
Severity of the disease condition			
Life-threatening condition and or disability may be occurred in the absence of the item.	Yes	Occasionally	Rarely
Difficult to treat the disease condition in the absence of the item; however can be tackled by a substitute.	Rarely	Yes	Rarely
Therapeutic significance			
Effective against less severe but significant illness.	Rarely	Yes	Rarely
Treats minor, self-limited Symptoms and conditions.	No	Possibly	Yes
Crucial to the service			
Health service will be discontinued in the absence of the item.	Yes	Rarely	Not at all

B. ABC Analysis

ABC value analysis is a method for determining and comparing pharmaceutical costs within the health facility. It follows the Pareto principle *"separating the vital few from the trivial many in terms of budget consumption/allocation"*. ABC Analysis can be explained in terms of budget consumed and number of medicines in the budget list as follows:

Category	Percentage of Budget	Percentage of Drugs Orders
-A‖ Drugs	70-80%	10-20%
-B‖ Drugs	15-20%	10-20%
-C‖ Drugs	5-10%	60-80%

"A" medicines:

- High percentage of funds spent on large-volume or high-cost items
- Greatest potential for savings
- Greatest potential for identifying expensive medicines that are overused

"B" medicines:

- Moderate cost and moderate number of items; important items

"C" medicines:

- Small amount of funds spent on the majority of the inventory

Steps for Conducting ABC Analysis

Note the following points before conducting ABC analysis:

- Exclude medicines received by donations and permanent goods like medical equipments from ABC analysis.
- If a single medicine is supplied both by donation and purchase in a particular year and thedonation is not continuous, then this donation may have impact on medicines budget allocation by the facility. In this case donated medicines have to be accounted together with purchased medicines during ABC value analysis.
- ABC analysis can be conducted separately for donated medicines.
- It is advisable to perform ABC value analysis based on three consecutive years receiving/purchased data of a specific health facility for the first time. For subsequent years, the facility should conduct ABC value analysis using yearly budget consumption. This data is obtained from receiving voucher.

NB: The data of each year should be registered and analyzed using excels sheet.

❖ Standard operating principle for ABC/VEN Analysis

Step 1: Define the names of drugs to ensure utilization of uniform nomenclature across the entire product list. E.g. use disposable glove or examination glove. List all items purchased/received during the year and their respective units using excel sheet using the template shown under Step 3.

Step 2: Write the total quantity and unit cost of each item purchased or received, and thereceiving date, receiving voucher number and expiry date.

Step 3: Calculate the total cost of each item purchased or received by multiplying the totalquantity by the unit cost.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	Receiving date(EC)	Receiving voucher serial number	Expiry date
1	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	2/7/2009	14524	Mar-18
2	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	2/7/2009	12374	Jan-19
3	Amoxicillin 500 mg of 100	box	5000	100	500000	2/7/2009	17869	Dec-17
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	2/7/2009	11234	Jun-18
5	Tetracycline 250 mg of 100	pack	1900	70	133000	2/7/2009	98534	Oct-18

Step 4: Sort the list alphabetically. Before sorting, make sure that all lists of medicines along the product name entry are registered/entered left indented in the column. Check whether all medicines are sorted alphabetically.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	Receiving date(EC)	Receiving voucher serial number	Expiry date
3	Amoxicillin 500 mg of 100	box	5000	100	500000	2/7/2009	17869	Dec-17
2	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	2/7/2009	12374	Jan-19
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	2/7/2009	11234	Jun-18
1	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	2/7/2009	14524	Mar-18
5	Tetracycline 250 mg of 100	pack	1900	70	133000	2/7/2009	98534	Oct-18

Step 5: Aggregate same medicines and add their total costs under the total cost column (if purchased more than once). Same medicines are those with the same generic name, strength and dosage form but may have different brands, pack sizes, period of purchases, sources and unit prices. At this step, the data entry will end up with three columns only; S/N, Descriptions (generic name, strength, dosage form) and Total cost.

N.B.: ABC value analysis can be performed for each drug or for therapeutic category. Aggregating drugs by therapeutic category involves aggregating antibiotics, non-steroidal anti- inflammatory drugs, anti-diabetics, antihypertensive etc. as a group and make analysis.

Step 6: Sort the list based on the total cost in a descending order so that the largest cost or value item will be on the top and the lowest at the bottom.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	Receiving date(EC)	Receiving voucher serial number	Expiry date
3	Amoxicillin 500 mg of 100	box	5000	100	500000	2/7/2009	17869	Dec-17
5	Tetracycline 250 mg of 100	pack	1900	70	133000	2/7/2009	98534	Oct-18
1	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	2/7/2009	14524	Mar-18
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	2/7/2009	11234	Jun-18
2	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	2/7/2009	12374	Jan-19

Step 7: Calculate the overall cost of all items purchased or received by adding the total cost ofall items.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost
3	Amoxicillin 500 mg of 100	box	5000	100	500000
5	Tetracycline 250 mg of 100	pack	1900	70	133000
1	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000
2	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400
	Total cost				904620

Step 8: Calculate percent total cost of each item by dividing the total cost of each item by theoverall cost of all items and multiplying the result by 100.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	% Total cost
3	Amoxicillin 500 mg of 100	box	5000	100	500000	55.28
5	Tetracycline 250 mg of 100	pack	1900	70	133000	14.7
1	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	14.5
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	13.82
2	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	1.7
	Total cost				904620	100

Step 9: Calculate the cumulative percent total cost of each medicine. In completing the cumulative percentage, take the first entry (medicine with the largest percentage value) as it is and add the percentage of the second entry to the percentage of the first entry to get the cumulative percentage of the second entry and continue doing the same for the rest. Make sure that the cumulative percentage of the last entry is 100%.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	% Total cost	Cumulative % Total cost
3	Amoxicillin 500 mg of 100	box	5000	100	500000	55.28	55.28
5	Tetracycline 250 mg of 100	pack	1900	70	133000	14.7	69.98
1	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	14.5	84.48
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	13.82	98.3
2	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	1.7	100
	Total cost				904620	100	

Step 10: Calculate percent order by dividing the number of items for each row by the total number of items.

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	% Total c	Cumulative % Total cost	% Order
1	Amoxicillin 500 mg of 100	box	5000	100	500000	55.28	55.28	20
2	Tetracycline 250 mg of 100	pack	1900	70	133000	14.7	69.98	40
3	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	14.5	84.48	60
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	13.82	98.3	80
5	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	1.7	100	100
	Total cost				904620	100		

Step 11: Determine the cut-off points for A, B and C classes based on the cumulative % totalcost and order and categorize the list of items accordingly. The cut-off point should be determined in such a way that both the cumulative percent and % order ranges are taken into consideration.

- –A‖ class – 10 to 20 % of items that takes 70-80% of the overall total cost
- –B‖ class – 10 to 20 % of items that takes 10-20% of the overall total cost
- –C‖ class – 60-80% of items that takes 5-10% of the overall total cost

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	% Total c	Cumulative % Total	% Order	ABC category
1	Amoxicillin 500 mg of 100	box	5000	100	500000	55.28	55.28	20	A
2	Tetracycline 250 mg of 100	pack	1900	70	133000	14.7	69.98	40	B
3	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	14.5	84.48	60	C
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	13.82	98.3	80	C
5	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	1.7	100	100	C
	Total cost				904620	100			

Step 12: Insert the VEN category of each item and reconcile the results (refer the section on ABC/VEN reconciliation below).

SN	Description (Drug name in generic, strengh, dosage form, pack size)	Unit	Quqntity	Unit cost	Total cost	% Total c	Cumulative % Total	% Order	ABC category	VEN category
1	Amoxicillin 500 mg of 100	box	5000	100	500000	55.28	55.28	20	A	E
2	Tetracycline 250 mg of 100	pack	1900	70	133000	14.7	69.98	40	B	N
3	Sodium chloride 0.9 % 1000 ml	bag	3600	36.45	131220	14.5	84.48	60	C	V
4	Hydrochlorothiazide 25 mg of 100	box	2500	50	125000	13.82	98.3	80	C	E
5	Diazepam 10 mg/2 ml	ampoule	4000	3.85	15400	1.7	100	100	C	V
	Total cost				904620	100				

C. ABC/VEN Reconciliation

ABC/VEN reconciliation builds on ABC analysis. It involves sorting the list of medicines in the ABC analysis by VEN so as to identify whether there is relatively high expenditure low priority medicines (N category items in –A‖).

Steps in ABC/VEN reconciliation

- Present results of the ABC-VEN analysis to DTC for discussion to check whether drugsin the –A‖ class reflects public health problem of the area.
- Undertake drug use evaluation (DUE) on the medicines suspected to be overused that fallunder class –A‖.
- Determine the % of drugs purchased according to the medicines list of the facility
- Take appropriate measure on those medicines which fall in A class in ABC analysiswhile they are N in the VEN analysis.

The table below shows characteristics of medicines that fall into each category of ABC and theactions that should be taken.

S/N	Class –A‖ items (High value)	Class –B‖ items (Moderate value)	Class –C‖ items (Low value)
1	Needs very strict control up on Purchasing	Needs moderate control	Needs lose control

2	High percentage of funds (70%-80%) spent on few type (10%-20%) due to large- volume of each items or high	Either moderate cost or moderate number of items; important items	Small amount of funds (5%-10%) spent on the majority of the inventory (60%-80%)

S/N	Class –A‖ items (High value)	Class –B‖ items (Moderate value)	Class –C‖ items (Low value)
	cost of each items		
3	No or very low safety stock (small amount purchase)	Low safety stock	High safety stock
4	Greatest potential for identifying expensive medicine and greatest potential for negotiation during purchasing	Moderate potential for negotiations and saving of budgets	Very less potential for saving of budget (all 5%-10%) up on negotiation
5	Should be either vital or essential when reconciled withVEN	May be either vital or Essentialwhen reconciled with VEN	May not need to be Essential or vital when subjected to VEN
6	If it becomes N in VEN analysis, it should be subjected to stock status analysis to prove whether it will be consumed within the limit of expiry date of the drug. Ideally it should be either V or E	It can be either E, V, or N. conditions can determine its value and consumptions. Ideally it should be E	If V or E in VEN analysis, it should be subjected to SSA to prove its continuity in supply. Ideally it should be N
7	Maximum follow-up and expediting the supply andutilization	Periodic follow-up	Follow-up and expediting in exceptional cases

	process		
8	Rigorous value analysis	Moderate value analysis	Low value analysis
9	Should be subjected to stock status analysis (SSA)	If E in VEN analysis, it may besubjected to SSA	If N in VEN analysis, it may not need to subject to SSA
10	Purchase Carefully handled	Purchase can be handled by middle management	Purchase can be fully delegated (petty cash)
11	Frequent ordering or weekly	Once in three months	Bulk ordering once in 6

S/N	Class –A‖ items (High value)	Class –B‖ items (Moderate value)	Class –C‖ items (Low value)
	delivery		months
12	Weekly control statements relate with the daily sales auditreport	Monthly control reports	Quarterly control reports
13	Accurate forecasts in material planning	Estimates based on past date	Rough estimate for planning

SUMMARY

Inventory control system is the system of maintaining adequate stock levels of all pharmaceuticals in a certain facility. The main aim of this system is to inform the store man or other concerned body when and how much of a pharmaceutical to order/issue and to maintain an appropriate stock level to meet the needs of patients and to prevent wastage of pharmaceuticals and budget.

To meet the objective of inventory control system, there are different types of terminologies we should consider and types of inventory control systems that are currently practiced in different health facilities. There are also different types of ordering and reporting formats (to exchange information and pharmaceuticals from higher to lower health facility and vice versa) you have seen and practiced in this chapter like; HPMRR, IFRR, and RRF. But the concept of ABC/VEN analysis differs from this because ABC/VEN analysis result is not only for reporting and ordering. It is used also for budget allocation in the facility and to prioritize items during purchase (to select which items should be first and which should be next) based on budget and disease prevalence (consumption pattern).

CHAPTER 8: Logistics management information system

By the end of this chapter students will be able to:

- Define logistics management information system (LMIS)
- Explain the importance of LMIS
- Describe essential data needed for decision making
- Discuss types of logistics records
- Explain the reporting systems, summary reports, and feedback reports
- Demonstrate stock recording and reporting

8.1 Logistics Management Information Systems

A logistics management information system (LMIS) is the system of records and reports that one uses to collect, organize, and present logistics data gathered across all levels of the system. An effective LMIS enables people involved in health product management to make informed decisions that will ultimately improve medicines availability to patients.

Information is the engine that drives the entire logistics cycle. We collect information to make decisions; the better information we have, the better decisions we can make.

The LMIS can be used to make decisions in the areas like quantification, procurement, calculating maximum stock level and reporting, inventory management and control at the health facility level, monitoring program performance, national pipeline monitoring, redistribution of health commodities when necessary, and capturing information on where consumption is highest or lowest, which helps determine whether more resources are required.

An effective LMIS for medicines will thus contribute to preventing stockouts and stock imbalances of medicines at health facilities. However, it heavily relies on good record- keeping practices of the staff responsible for medicines management at health facilities.

For an effective LMIS, the following six key elements which are also known as the logistics six rights are needed.

1. the right data (also called the essential data items)
2. at the right time (in time to act)
3. at the right place (the place where the decisions are made)
4. in the right quantity (having all essential data from all facilities)
5. the right quality (we must believe that the data are complete and accurate)
6. at the right cost (we should not spend more to collect information than we spend onsupplies).

1.2. Essential Data for Decision Making

If data are to be collected for decision making, you need to know what data to collect and how frequently to collect it. To decide what data to collect, look at the decisions you will need to make. Think about the questions logistics managers might ask. What information would they need to answer those questions and make informed decisions? The questions might include the following:

- How long will current supplies last? When do we need to order more supplies?
- Where are our supplies in the pipeline? Do we need to move supplies from higher tolower levels?
- Where is consumption the highest? Do those facilities need more resources?
- Are we losing products from the system that require us to take action?
- Are supplies flowing smoothly through the pipeline? Do we need to adjust our pipeline toaccount for bottlenecks in the distribution system?
- Are any products about to expire? Should we take them out of the pipeline? Can weredistribute them; can they be used before they expire?

To manage a logistics system and to make supply decisions, three MINIMAL and ESSENTIALpieces of information that must be recorded as well as reported through the LMIS are needed:

- **Stock on hand**: Quantities of usable stock available at any level or at all levels of thesystem at a point in time.

Examples;

- ✓ The health center has 300 bottles of paracetamol in the store on the last day of themonth.
- ✓ At a national level, 780,000 bottles of paracetamol are on

hand, based on stockon-hand data from the health centers, districts, and national warehouse.

- **Rate of use (consumption):** The average quantity of commodities dispensed to users in agiven time.

Examples

✓ In the last month, the health center used 120 Determine HIV tests. In the lastmonth, the health center dispensed 1,045 condoms to clients.

- **losses and adjustments:** Losses are the quantity of health commodities removed from the distribution system for any reason other than consumption by clients (e.g., losses, expiry, and damage). Adjustments may include receipt or issue of supplies to/from one facility to another at the same level (e.g., a transfer) or a correction for an error in counting. Losses/adjustments may, therefore, be a negative or positive number.

Examples

✓ In the past month, the district hospital had

- 30 male condoms expire (loss)
- 4 IUDs stolen (loss)
- Loaned another health facility 12 packages of oral rehydration salts(negative adjustment).
- Received 20 treated malaria nets from another health facility (positiveadjustment).

1.3. Logistics Records

In the supply pipeline, supplies are stored, moved (in transit), or consumed (used). In order to monitor and track supplies in the pipeline, three types of records are needed.

1. **Stock keeping records**

They keep information about products in storage and they must contain stock on hand, receipts, issues, losses, and adjustments, by individual product. Anyone who receives or issue stock from storage and takes a physical inventory should complete the stock keeping records. Since products are not distributed (dispensed) directly from the storeroom to the customer; therefore, actual consumption data is not collected on a stock keeping record. Issues data recorded at the lowest- level stock keeping record can be a

substitute for consumption data, if those data are not available (for example, from a facility store to the dispensary). When the stock keeping record is full, a new record should be started using the ending balance from the previous record. Stock keeping records are completed by;

- anyone who receives or issues stock from storage,
- anyone who takes a physical inventory of the stock, including the warehouse manager and other warehouse staff, and service delivery point (SDP) staff.

They are recorded on the stock keeping record whenever products are received or issued, when stock is counted during a physical inventory, or as soon as a loss is noticed. When the stock keeping record is full, a new record is started, using the ending balance from the previous record. Data on stock keeping records are organized by date and transaction reference (the unique number of the corresponding transaction record for a receipt or issue, and/or the name of the facility from which products are received and issued). They record receipts, issues, losses and adjustments, and the balance on hand.

The most common formats for stock keeping records are individual stock cards and stores ledgers. Types of stock keeping records include stock cards, inventory control cards, and bin cards.

Bin card: is an individual stock keeping record that holds information about a single product by lot number or batch number (figure 9.3.1). Every item in that lot will have the same expiration date. For example, one bin card would hold information about a single lot of paracetamol at a storage facility. The card should note the stock on hand of paracetamol for that lot only, as well as any losses and adjustments for that lot. Bin cards are usually displayed at the bins (or shelf or pallet position) where the lot is found.

A **stock card** is an individual stock keeping record that holds information about a single product by lot number or batch number (figure 9.3.2.). The card should note the stock on hand, losses andadjustment of a product for that batch number only. An inventory control card is an individual stock keeping record that holds information about all the lots of a single product, it can also be known as a summary of many bin cards for a product. To ensure each lot is managed correctly in large warehouse, it usually advised to maintain

Should losses be tracked separately from adjustments?

both inventory control cards and bin cards. In small storerooms, stock keeping record or stock card or inventory control cards can be used.

Stores ledger is a stock keeping record that contains the same information as the stoke cards described above. Unlike stoke cards, a stores ledger is bound like a book; it is used instead of theindividual card format. Government policy in some countries requires the use of stores ledgers.

(Managers may think that binding the pages increases accountability, because missing pages are obvious.) However, the ledger format is less desirable than individual cards, because it is easy to run out of space for an individual product. It is also hard to add new products—you can alphabetize a set of individual inventory control cards as new cards are added, but you cannot alphabetize pages within a bound book. (See figure 9.3.3.)

BIN CARD								
Commodity Lot/ Batch No.:				Proct Name & Description:				
Unit:				Expiry Date :				
Date	Transaction Reference	Received from/Issued to	Quantity Received	Quantity Issued	Losses	Adjustments	Quantity on Hand	Initials

Figure 9.3.1. Bin card

Name of Health Facility: _____

Product Name, Strength and Dosage Form _____

Unit of Issue: _____ Location: _____

Maximum Stock Level: _____ Emergency Order Point: _____

Average Monthly Consumption (AMC): _____

Date	Doc. No. (Receiving or Issuing	Received from or Issued to	Quantity Unit Price				Price		Expiry Date	Remarks
			Received	Issued	Loss/Adj	Balance	Birr	Cent		

2. Transaction records

Transaction records are used to record information about the movement of stock from one storage facility to another. In addition, transaction records are proof of requisition, issue, and/or delivery. Sometimes, a transaction record will be combined with a type of report and will include data like current stock on hand and, depending on the system design, losses and consumption data. Transaction records are completed by warehouse personnel at both issuing and receiving facilities. In pharmacies, storekeepers, pharmacy personnel, or nurses may complete the transaction records. These transaction records are started any time a facility requests or issues supplies. They are filled in at any point in the order, issue, and receipt process when custody of the product being moved changes. They are completed when the receiving facility confirms receipt of the items shipped. The data on a transaction record are usually organized by date and by transaction number, which helps to identify the transaction. Extra copies of transaction records can be a reminder that a request was made and not yet received, or that an item was

issued, but confirmation of receipt is still pending. Ideally, transaction records should include a reference number that identifies each transaction. Data on the transaction record are organized bythe product requested or issued. One transaction record is usually used to request or issue any number of products. On paper transaction records, the product names may be pre-printed or written by hand.

The most common formats for transaction records are bills of lading; receiving records; issue vouchers; receipt vouchers; and combined requisition, issue, and receipt vouchers. The content of the transaction record will depend on how many transactions and which parts of the transaction are tracked on the record. The format of the transaction record may also depend on whether the system is pull or push. In all cases, a pre-printed voucher number on each transactionrecord helps track individual shipments.

An issue and receipt voucher (IRV) lists the items and quantity issued to a facility. It also includes a separate column for the quantities received in case any items are lots or damaged en route. IRVs are used in a push system; the issuing facility determines the quantity to be sent and issues the supplies to the receiving facility. See figure 9.3.4. for a sample IRV. An IRV should becompleted in triplicate (three copies).

1. The issuing facility completes the date and quantities issued, signs the voucher, andsends the top two copies (1 and 2) to the receiving facility, with the supplies. The bottom copy (3) is often called the reminder copy because the issuing facility keeps the bottom copy of the issue voucher as a reminder that it is waiting for verification that the supplies were received.
2. The receiving facility verifies the quantity received, signs the form, and returns the top copy (1), and keeps the middle copy (2) for its files.
3. The top copy (1) arrives at the issuing facility, which then disposes of the reminder copy

(3) and keeps the top copy for its files. Each of the facilities will have a completed copyof the IRV for its permanent file. All copies of the IRV are labeled with the same transaction number so there is no confusion when either facility manager needs to talk to the other manager about a problem with the shipment.

ISSUE AND RECEIPT VOUCHER

Issue Voucher No.: _____

Date: _____ Ship to: _____

_____

_____

	ARTICLE	Quantity		REMARKS
		Issued	Received	
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

Approved by: _____ Date: _____

Shipped by: _____ Date: _____

Received by: _____ Date: _____

Figure: Issue and Receipt Voucher

A requisition, issue and receipt voucher (RIRV) is similar to an IRV, except that the RIRV is used only in a pull system (if it is completed by facility staff) (see figure 9.3.5). An RIRV lists the items and quantities requested by a facility. It also includes a column for the quantity actually issued. This is important in situations when it is impossible to supply the full amount requested. Like an IRV, the RIRV includes a column for the quantity received, which helps to account for any losses or damage en route.

Between two levels, RIRVs should be completed in quadruplicate for requisition (pull) systems.

1. The requesting facility completes the date and quantities requested for each item, signs the record, and sends the top three copies (1, 2, and 3) to the issuing facility; they keep the bottom copy (4) as a reminder that it has placed an order and is awaiting its arrival.
2. The issuing facility fills the order, signs the form, and sends the top two copies (1 and 2) to the receiving facility, with the supplies; they keep the bottom copy (3) as a reminder.

3. The receiving facility signs the form, verifies the quantity received, and returns the top copy (1). The receiving facility keeps the second copy (2) for its files and disposes of the reminder copy (4).

4. The top copy (1) arrives at the issuing facility, which disposes of the reminder copy (3) and keeps the top copy for its files. Each of the facilities will have a completed copy of the RIRV for its permanent file. Because the transaction has only one RIRV number at both facilities, there should not be confusion when referring to the shipment.

In addition to the item description and quantity of each item being moved, all transaction records should include dates, signatures, and a space for comments. The signatures indicate responsibility for and authorization of a transaction (by, for example, an accounting department or program manager). Limit the number of required signatures on a transaction record, if possible, to reduce the administrative burden and time spent collecting signatures. A space for comments should be available for recording any reason why the quantities shipped are different from the quantities received.

REQUISITION, ISSUE, AND RECEIPT VOUCHER

Issue Voucher No.: _____

Date: _____ Ship to: _____

	ARTICLE	Quantity Requested	Issued	Received	REMARKS
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

Approved by: _____ Date: _____

Shipped by: _____ Date: _____

Received by: _____ Date: _____

Figure: Requisition, Issue, and Receipt Voucher

3. Consumption records

They are used to record the quantity of each product used by or dispensed to end users, or used at an SDP when services are provided. Consumption records contain consumption data; more specifically, the quantity of any specific product consumed in a specific period of time and service providers who dispense products to clients or use products at SDPs are the one who should complete the records. They do not usually record stock on hand, or losses and adjustments.

Consumption records filled out whenever supplies are dispensed to clients or used by service providers during service provision. The total quantity of each product used or dispensed is totaled at the end of the reporting period. The data on a consumption record is organized usuallyby the date of the visit, or date of dispensing or usage. They record the quantity of a specific product either dispensed to users or used by the end user. The consumption records are usually bound in a book or are printed on oversized paper. One record (perhaps consisting of several pages) is usually used per month; however, in a bound book, a new page is started each month. Common formats include daily activity registers (DARs), pharmacy dispensing registers, daily usage registers or logs, and tick sheets.

A daily activity register (DAR): records the quantity of each product received by a customer(by name or client number) and by date. They work best when the brands (for family planning programs) or the names/strength/ formulation of each product (for medicines) are pre-printed on the form. At the bottom of the DAR, the total quantity dispensed or used is calculated for each product and then used for reporting purposes. Another name or example of a DAR is a Daily Dispensing Register.

A daily usage log or register: used to record the quantities of a product, usually related to the laboratory, that facility personnel use on a particular date; for example, the number of HIV tests used in the HIV counseling and testing department on a particular day, or the number ofvacutainers used in the lab on particular day. These usage logs also work best when the products are pre-printed, by brand, on the form.

A tick sheet: It is used to record the quantity of each product dispensed to users. A tick or mark (often an X) indicates one unit dispensed. In some cases, each box represents a client, and the number of each item dispensed is written in the box. A tick sheet does not

record this information by day or by client.

Relationships among data found in records

At the SDP, the consumption data recorded on the DAR should be close to the issue quantities recorded on the inventory control card (ICC). Also, the transaction numbers on an RIRV or IRV should match the numbers recorded on the ICC. Periodically, logistics managers should verifythe quality of the data. Maintaining accurate records is crucial to good supply chain management. At any level of the system, managers should be able to quickly and easily report the stock on hand for any item. In a small warehouse, this may mean walking to the storage area and reading the numbers from a conveniently located stock card. In a large warehouse, this may mean being able to find the ICC file quickly, or to look it up data in a database. The entire transaction should be clear—who placed the order and when, when the order was filled and shipped, and when the order was received. If questions arise, you should be able to trace a transaction by using the reference number from the stock keeping records to locate the transaction records.

1.4. Reporting Systems and Summary Reports

Data recorded on stock keeping, transaction, and consumption records should be available to managers in a form useful for decision making. To make a good decision it is reasonable for logistics managers to get the right data (the essential data items), at the right time (in time to take action), at the right place (the place where the decisions are made), and in the right quantity (having all essential data from all facilities). The data must be of the right quality (we have to believe that the data are complete and accurate) and at the right cost (we should not spend moreto collect information than we spend on supplies). Therefore, reports are used to move the essential data to decision makers.

Reporting systems

Reports move information up and down through a logistics system and provide decision makers at various levels the right information, at the right time, in the right place, in the right quantity, ofthe right quality, and the right cost. A reporting system must be in place to ensure that this information flows correctly and consistently. A reporting system in a supply chain may include levels outside storage and distribution points. For example, a District Health Office might not hold stock or be involved in the distribution of products, but this office still needs to receive LMIS reports to ensure that facilities are stocked

appropriately to determine if the District HealthOffice needs to invest additional funding and/ or resources into training, staffing, commodity quantities, etc. Figure 9.4.1 is an example of a reporting system that includes both summary reports and feedback reports. It also highlights how the different levels that are involved inbudget and supervision decisions but not necessarily in direct stock management and distribution also need logistics information to make decisions.

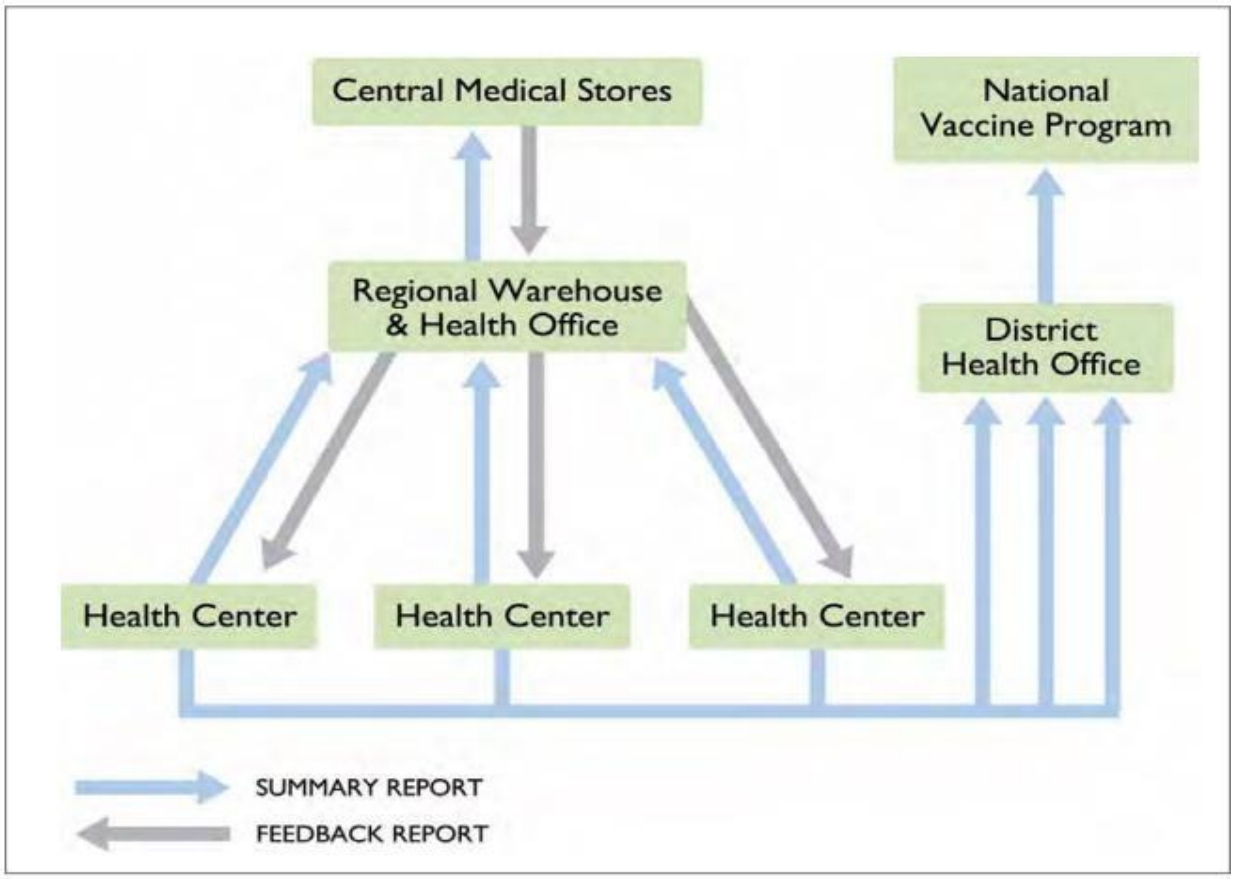

Figure: Sample Logistics Reporting System: National Vaccine ProgramSummary reports

Summary reports are used to move all essential logistics data items for products, for a specific facility, and for a specific time period (such as monthly, bimonthly, or quarterly) to the decision makers. They must contain all three essential logistics data items; stock on hand, consumption, and losses. Adjustments may also be reported, if useful for decision making, but reported separately from losses. Summary reports are usually completed at the end of the reporting period (usually monthly, bimonthly, or quarterly) by the manager responsible for collecting the three essential logistics data items. One summary report is usually prepared and submitted for or by each facility required to report, for a specific period. Lower-level facilities are usually given a reporting deadline, and each successive level is given another deadline for reporting to the next level. For example, health facilities may be given until the 10th day of the following month to report to districts, districts may have until the 20th day to report to the region, and the region may have until the last day of the month to report to the central level. Some countries stagger their

reporting schedules. For example, in a staggered, bimonthly reporting system, half the lower-level facilities would report one month and the other half would report the next month. This has the advantage of decreasing the reporting burden at the lower-level facilities, because they only need to report every other month. The burden of work at the next level is also half, as they only need to review half the number of reports in a given month. Staggering bimonthly reporting evens out the work load over the year. Staggering reporting, however, has implications in terms of aggregation of data, supervision schedules, and delivery management. For aggregating data, you may have to wait for an extra month before total consumption data is available. The data on summary reports are usually organized by date—monthly, bimonthly, or quarterly, depending on the reporting cycle. Most often, they report the beginning stock on hand, receipts, the quantity issued or dispensed, losses and adjustments, and the end stock on hand for a specific time period. The most common formats for summary report include simple facility reports, aggregate facility reports, and combined report and request forms.

Aggregate summary report

One of the most important decisions logistics managers face in collecting data on summary reports is determining when and at what level data can be aggregated. What data should be aggregated, and at what level, depend on many factors.

- First, how visible does the facility-level data need to be higher up in the system (i.e., does the central level need to know exactly what each health facility distributed and has on hand?)?
- Second, what decisions need to be made at what levels (budgetary, supervision, stock distribution, etc.) and what detail of data is needed?
- Third, what are the current tasks and work responsibilities of staff that will be required to compile the aggregated data? Will aggregating data be too much of a burden? Which levels have tools (computers) and staff that can more easily aggregate data?

Consider a pipeline of three regions, each with two districts, and each district with four health centers. The health centers forward their reports monthly to the district. The district then reports to the region in one of three ways:

1. Include information for the district store-room only on the report, and

then include a copyof each health center‘s report separately.

2. Include information for the district store-room only on the report, and then add all the health center data together on a second report.

3. Add data for the district and health center together, but, under the column issued/dispensed, report only the aggregate dispensed-to-user data from the clinics (without including the issues data from the district to the health centers).

With any of these three methods, the regional level will receive all the essential logistics dataitems for the district.

A combined report and request form

This is a summary report that presents the data to the next higher level and requests newsupplies. The advantage of this report are;

- The higher level can verify the need, and
- The lower level sends up only one form that includes both its reporting data and its order.
- Reporting rates often improve because when a report is tied to an order, it usuallyencourages timely submission of reports.

A report and request form (or Report and Requisition) is sometimes combined with an Issue and Receipt Voucher and is useful for other steps in the transaction. Facilities are more likely to submit their reports when they receive something (resupply) in return. If reports and orders are linked, it is important to consider that the frequency of reporting dictates the frequency of

distribution (i.e., if reporting is monthly, then distribution must be monthly). The issuing facility must have the infrastructure and capacity to distribute products as often as it receives reports.

Summary reports should always include a place for comments, particularly explanations for any losses and adjustments. The person completing the report must sign and date the report. At higher levels in the system, the summary report could also indicate the completeness of the report. For example, the report may indicate that 100 reports were expected, but only 92 were received. Knowing this, a manager at the next higher level can determine how well facilities are reporting and then make mathematical adjustments for the missing data.

How summary do reports move?

They move up the pipeline from the SDPs to the central level. Depending on where reports are aggregated, reports from SDPs may move all the way to the central level or may be kept at the level at which they were aggregated. Summary reports that are also tied to requisitions (order) may bypass reporting to intermediate levels and report directly to higher levels, usually from where supplies are issued—like a district store or central warehouse. This has the effect of shortening the lead time for reporting. However, other levels may still need to see the summary report for supervision, pipeline monitoring, and budgeting purposes. In addition, reporting lead time can be shortened significantly if reports are transmitted electronically—either through email, mobile phone, or a website/LMIS database. Electronic reporting also decreases the possibility of a report being lost during transit.

• 1.5 Feedback reports

When program and logistics managers know the data they received are incorrect, they need to communicate with the facility that sent the data. Managers can also use data they receive to congratulate facilities for moving toward program goals. To do this, managers can use feedback reports (see figure 9.5.1); these reports are important for facilities and managers, as well as for stakeholders at other levels of the supply chain, especially the central level. Feedback reports aggregate and analyze the data contained on the routine LMIS reports submitted by facilities. These central-level reports often contain information on trends in consumption, national stock status, percentage of facilities reporting, and percentage of facilities experiencing a stockout. Use

feedback reports to identify overall logistics system weaknesses or issues to inform overall program planning and management, and areas for logistics system improvement. Preparing feedback reports is easiest when the LMIS is automated. Computers quickly identify mathematical errors and highlight missed deadlines; list the percentage of expected reports received; and search for data averages, highs, and lows. Feedback reports are essential for manual systems too, but processing and preparing reports by hand may require a great deal of time and effort. All logistics systems should be designed with feedback mechanisms.

Feedback for facilities

Feedback reports inform lower levels about their performance; improve capacity; give recognition; and, in some cases, provide information about reporting from other facilities. Feedback reports also inform managers at higher levels about how the system is functioning. Feedback reports may help solve many problems. For example, when summary reports are self- balancing, it is easy to pinpoint errors in the individual reports. Feedback reports can include information about these errors and how to correct them. In addition, feedback reports let the person sending the report know their work has been received (and when it was received). Also, feedback reports can be used to motivate lower levels to turn in complete, error-free reports, on time, by reporting which sites are producing quality reports and which are not.

Feedback for decision makers throughout the supply chain

Managers can use feedback reports to gauge how well the system is functioning. For example, a feedback report might list facilities that are stocked out or overstocked; percentages of those facilities reporting at each level; or quantities of losses and adjustments, by level. Feedback reports can also address a single facility or product. In addition to providing feedback to facilities, the feedback reports are used to present data for decision making throughout the supplychain. The decision makers might be divisions within the public sector, such as Ministry of Health, government procurement units, warehouses (such as the Central Medical Stores [CMS], or distributors [if third party logistics are being used]). Other donors, funding agents, implementing partners, and NGOs can also be decision makers within a system and can benefit from using feedback reports. A key element of feedback reports, whether they are sent to a facility or the CMS, is that they increase visibility of information by communicating logistics data to all levels of the system.

Using an LMIS for Decision making

At the most fundamental level, the decision making process can be viewed as a black box into which information flows and out of which decisions emerge. Although simplistic, figure 9.5.2 shows what logistics managers actually do; it illustrates some important points that are frequently overlooked in LMIS development. Which are;

- If you are interested in decisions of any type, you must understand the decision making process.

- To improve decisions, you could (1) improve the information flowing into the box, or (2) improve the process within the box. These are two different types of activities; in most cases, to have any effect on decisions, the two must be done simultaneously.
- It is not possible to define better information without understanding both the decisions being made and the decision making process. This is the most important principle of LMIS development: to design a relevant, useful system, you must first consider what decisions are being made and, second, how they are being made. Only with this understanding can you say what information is needed and how to collect it. Information systems fail most frequently because the information they collect is not useful in decisionmaking.

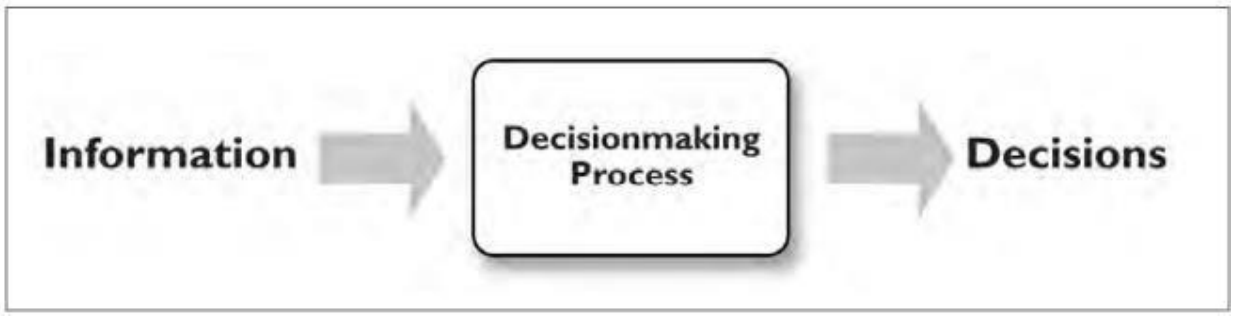

Figure 9.5.1: Decision making Process

Quality monitoring of the logistics management information system

Quality monitoring is necessary because the essential data needed for logistics management are used to make informed decisions that will improve customer service, quality is critical; in fact, data quality is one of the six rights for LMIS data. Although data quality is often a challenge, there are specific steps that can be taken to improve the quality of LMIS data:

- **Data collection**: All staff responsible for maintaining logistics records: whether stock- keeping, transaction or consumption should be appropriately trained and have adequate time to carry out this responsibility. The forms should be clear and simple, with sufficient writing space. On-the-job training (OJT) and supportive supervision should beundertaken to ensure the forms are being completed correctly.
- **Data reporting:** Data should be reported regularly and logistics managers should review the reports to verify the quality of the data. Feedback reports and incentives can be used to motivate lower levels to turn in complete, error-free reports. Linking reporting with ordering also encourages timely reporting.
- **Data monitoring, aggregation, and analysis:** The data should be validated by comparing different reports to ensure that data are accurately and consistently entered, aggregated, and reported. It is important to ensure optimal quality of the raw data that is subsequently analyzed, so that reports are reliable for decision making.
- **Automated LMIS:** An automated LMIS; using computers, handheld devices, mobile phones, or the Internet can help improve data quality. It can help reduce mathematical errors; highlight missing information; and facilitate data capture, analysis, reporting, and feedback. However, computerized LMISs are expensive and require significant inputs (i.e., hardware, programming, electricity, training etc.); therefore, the quality improvement benefits must be weighed carefully against the costs.

Chapter 9: Stock Status Assessment

Chapter description

This chapter introduces students with the purpose of assessing stock status analysis and whenand how to assess stock status at any level in the system.

Chapter Objectives

Upon completion of this chapter, students will be able to

Apply stock status analysis

Discuss when and how to assess stock status at any level in the system

9.1 Assessing stock status

The purpose of assessing stock status is to determine how long supplies will last.

$$\frac{\text{How much we have of a certain product}}{\text{How much we use during a given period}} = \text{How long that product will last (in number of periods)}$$

9.2 When to assess stock status

The stock status should be assessed regularly for each product in the store room. Assessing the stock status recommended monthly for all products in store. Even if you only report or order quarterly, you should assess stock status more often to ensure that you are not at risk of a stockout. Stock status should also always be assessed during quantification exercises. If the number of products you store is large, you may not be able to assess the stock status for each product every month. In such cases, consider a vital, essential, non-essential (VEN) analysis, which categorizes products by public health priority; and/or an ABC analysis, which categorizes products by cost, and count a subset of products monthly, based on their importance and cost.

Frequent assessments of stock status are the best way to ensure that you are aware of the

potential for stockouts. Simply looking up at a shelf and making a decision without considering consumption data could lead to stockouts and, consequently, poor quality of care and customer service.

9.3 How to assess stock status at any level in the system

Assessing stock status can be expressed in terms familiar to logisticians. The amount we have is the same as stock on hand. The amount we use is the same as the rate of consumption. Becausestock assessment is measured in terms of months of stock (a convenient measure because dataare often collected monthly at the service delivery point

$$\frac{\text{Stock on hand}}{\text{Average monthly consumption}} = \text{Months of stock on hand}$$

[SDP] level), the average monthlyconsumption (AMC) more accurately describes the rate of consumption.

Assessing stock status at any level, or even all levels, can give you more than just a glimpse ofstock status in your own warehouse. You could also know whether—

- The levels you supervise are overstocked.
- The levels you supervise are understocked; additional shipments are needed.
- Any products will expire in storage before they can be dispensed to users.
- Some facilities have too much stock and others not enough.
- Supplies are reaching customers instead of sitting in warehouses.

- **Assessing stock status at higher levels**
-

When assessing stock on hand at the level above the service delivery point(SDPs) for example, atthe district level—you can see stock-on-hand data from one or more of the following three sources:

- ✓ District warehouse stock on hand
- ✓ Aggregate (sum) of the stock on hand at all service delivery point reporting to the district
- ✓ Aggregate of the stock on hand for the district warehouse plus the service delivery pointsreporting to the district.

Adjusting consumption data

When you assess stock status at the lower levels in the pipeline from the higher levels, you should base average monthly consumption (AMC) on actual dispensed-to-user data from the dispensing level (consumption data). These data can only come from service delivery points. However, you may encounter problems with consumption data: incomplete data because of a missing time period, or incomplete reporting or stock outs. When complete dispensed-to user datafor the last 3 months are not available, use one of the following techniques:

- ✓ Use the dispensed-to-user data from previous complete reports (older than three months).
- ✓ Adjust incomplete data to estimate complete reporting.
- ✓ Adjust for stock outs.
- ✓ For dispensed data, substitute issues data from the lowest possible level.

Adjusting data for incomplete reporting

At higher levels, collecting 100 percent of reports from SDPs (which include consumption data) may be challenging. Many systems experience these challenges because it is unusual to have all SDPs reporting on time. When this is the case and you want to assess stock status, you can use the consumption data that are available and adjust them to account for the missing data.

To adjust the data, divide the quantity reported by the percentage reporting, using the following formula:

$$\frac{\text{Sum of all consumption reported}}{\text{Percentage of reports received}} = \text{Estimated total consumption}$$

If you use this technique to estimate consumption, remember the following:

- ✓ Document how you made your adjustment.
- ✓ If reporting is very low, (for example, below 70 percent), substitute issues data for consumption data
- ✓ Not all SDPs are equal in terms of number of client visits or quantity of product dispensed. The basic technique described here assumes that consumption rates

for the missing SDPs are approximately the same as the SDPs that have been reported.

•

However, if SDPs that have not reported are very different from those that have reported (i.e., they are known to dispense much larger or much smaller quantities to users), you can Substitute issues data for consumption data, or you can adjust reported consumption data to reflect the percentage of total consumption that the reporting facilities represent. To adjust for incomplete reporting when the non-reporting sites are not similar in size to those reporting, use the followingformula.

$$\frac{\text{Sum of all consumption reported}}{\text{Percentage of consumption represented by those reporting}} = \text{Estimated consumption during period}$$

Adjusting data for stock outs

In gathering your stock on hand, or consumption data, you may discover that a stock out has occurred. In some cases, you may find that facilities have been rationing supplies to avoid a stock out or have been hoarding supplies (gathering large quantities) to avoid future problems. For established programs, if you know that a stock out, hoarding and rationing, or incorrect data reporting occurred in a particular month, you should disregard the data for that month and include data from earlier months when these events did not occur, until you have 3 monthsof data without such problems. You can use the following formula to determine an average of the (n) other periods and use that as the data for the stocked out period—

$$\frac{\text{Sum of consumption in other n periods}}{\text{Number of periods (n)}} = \text{Estimated consumption during period in which stockout occurs}$$

Using issues data instead of consumption data

You can substitute issues data for dispensed-to-user data when you assess stock status at higher levels, but this can be problematic. Issues data may overestimate consumption if

excessive quantities of product are being sent from one level of the system to another. Similarly, issues data could also underestimate consumption if products are being rationed. To minimize over or under-estimates of consumption, if issues data must be substituted for consumption data, it is best to collect issues data from the lowest level possible. For example, this could be the issues data from the facility store to the dispensary.

Adjusting stock-on-hand data

Similar to the situation described when adjusting consumption data, you may be in a situation when not all reports are received. When complete stock-on-hand (SOH) data for all facilities are not available, the stock-on-hand data must be adjusted for incomplete reports. This can be done in two ways, exactly as described when you adjust consumption data. Adjusting stock on hand by percentage reporting

- To do this calculation, divide the quantity of stock on hand reported by the percentage of thereports received.

$$\frac{\text{Sum of all SOH reported}}{\text{Percentage of reports received}} = \text{Estimated SOH at end of the period}$$

Chapter 9: Managing Rational Use of Medicines

Chapter description

This chapter equips students with the concepts of rational use of medicine. It describes the medicine use process, Rational use of medicines, causes and impacts of irrational use of medicine and strategies to promote rational use of medicines.

Chapter Objectives

Upon completion of this chapter, students will be able to:

- Describe medicine use process
- Explain the basic concepts of rational use of medicines
- Describe Causes of irrational use of medicines
- State the impact of irrational use of medicines
- Discuss the interventions strategies to promote rational use of medicines

2.11 9.1 The medicine use process

Medicine use is the process of prescribing, dispensing and patient use.

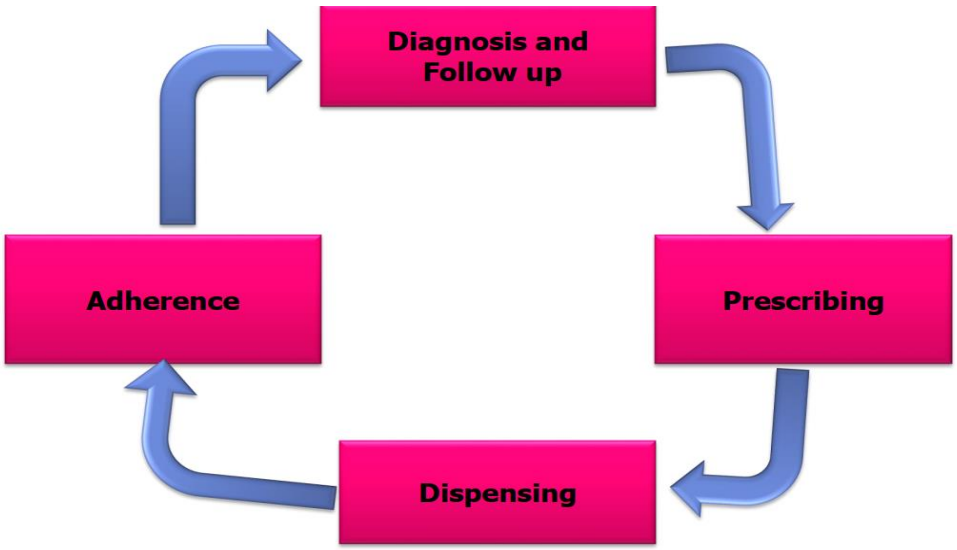

Figure 1: The medicine use process cycle

2.12 9.2 Rational use of medicines

According to the WHO, Rational use of medicines requires that "*patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community*".

Generally, rational drug use in a biomedical context includes the following criteria: correct drug; Appropriate indication- that is, prescribe on sound medical considerations; Appropriate drug, considering efficacy, safety, suitability for the patient, and cost; Appropriate dosage, administration, and duration of treatment; Appropriate patient, that is, no contraindications exist, and the likelihood of adverse reactions is minimal; correct dispensing, including appropriate information for patients about the medicines; and Patient adherence to treatment.

In short, for rational drug use all of the following four criteria should be considered; safety, effectiveness, appropriateness and economics (cost-effectiveness).

Rational drug use: - rational drug use promotes quality of care and cost-effective therapy, improves patient compliance, prevents unnecessary exposure to side effects and maximize therapeutic benefits

Components of Rational Drug Use

Rational drug use is promoted by:

1. Rational prescribing practice
    a. good diagnosis practice
    b. good prescribing practice
2. Rational dispensing practice
    a. good dispensing practice
    b. good stock management practice
3. Rational patient use

- Patient adherence/compliance

Rational Medicine use (RMU)

- **5Rs**
- ***If one "R" fails ⇨ it is irrational,***
- *The source of error could be from one of the actors (prescriber, dispenser and/or patient)*

NB: Rt: Right, admn: Administration, RMU: rational medicine use

2.13 9.3 Irrational use of medicines and examples

According to the WHO, "*irrational use of medicines implies that patients get medications inappropriate to their clinical conditions, doses not that meet their requirements for the desired period."* Irrational use of drugs may occur either due to irrational Prescribing, irrational dispensing, and irrational patient use. Irrational use of medicines is a major problem worldwide. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and

widespread health hazards. Examples of irrational use of medicines include: use of too many medicines per patient ("poly-pharmacy"); inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimens.

2.14 9.4 Types of irrational drug use

A. Irrational Prescribing: In irrational prescribing either the diagnosis or the treatment prescribed or both of them are wrong/ inappropriate as compared to appropriate standards of treatment.

Examples of irrational Prescribing

Extravagance: A less expensive drug would provide comparable efficacy and safety, symptomatic treatment of mild conditions diverts funds from treatment of serious illness, abrand name is used where less expensive equivalents are available.

Over-prescribing: this means drugs are used for conditions for which they are ineffective, the dose is too long or the treatment period is too long.

Incorrect prescribing: The use of drugs when no drug therapy is indicated. E.g. antibiotics for viral upper respiratory infections.

The use of wrong drug therapy for a specific condition requiring drug therapy. e.g., tetracycline in childhood diarrhea requiring ORS.

Multiple- prescribing: Two or more medications are used when one or two would achieve virtual the same effect

Under-prescribing: Needed medications are not prescribed, dosage is inadequate or length of treatment is too brief

B. Irrational dispensing practice

Commonly Observed Irrational Dispensing Practices are poor prescription review / interpretation, occasional dispensing of drug to wrong patient, substitution of prescribed drug (of different chemical entity/ dosage form) without the consent of the prescriber, dispensing in unhygienic condition/ materials, dispensing without clear verbal, written information and inadequate counseling time, poor stock storage, Poor inventory control and Poor stock management and dispensing of prescription drugs without prescription

C. Irrational use of drugs by patients

Compliance: Compliance is defined as the degree to which patients' behaviors (e.g., attending follow-up appointments, engaging in preventive care, following recommended medical regimens) correspond with the professional medical advice prescribed.

Common Types of Poor Compliance

The most common types of poor compliance by patients are: - Failure to take medication as prescribed: Not taking prescribed drugs at all, Reducing the dose, taking extra dose and Premature discontinuation

Misuse of drugs: Self-medication with prescription drugs Misuse of antibiotics Overuse of injection Taking medication whenever they feel ill Reserving medication for self-medication even antibiotics Sharing of drugs prescribed for others Using expired drugs Inappropriate storage

2.15 9.5 Causes of irrational use of medicines

Many different factors affect the irrational use of drugs. The major forces can be categorized as those deriving from patients, prescribers, the workplace and the supply system, and combinations of these factors.

Prescribers: - lack of objective drug information, generalization of limited experience, misleading beliefs about drug efficacy, lack of skill or conscientiousness, inadequate supervision, and lack of education and training are the prescriber related to irrational medicine use.

Dispensers: - Irrational medicine use associated with dispensers are insufficient training, insufficient staffing, lack of equipment and facilities, lack of packaging materials, poor attitude about dispensing, inability to interpret a prescription

Patients: **-** misleading beliefs, patient demands/expectations, no labeling or no understandable labeling, inadequate verbal instructions, complex treatment regimen or long, duration, presentation of treatment, drug misinformation

2.16 9.6 Impacts of irrational medicine use

The impact of irrational use of drugs can be seen in many ways:

- Reduction in the quality of drug therapy and overall quality of health care leading to increased morbidity and mortality.
- Waste of resources leading to reduced availability of other vital drugs and increased
- Increased risk of unwanted effects such as adverse drug reactions and the emergence of drug resistance, e.g., malaria or multi-drug resistant tuberculosis.
- Psychosocial impacts, such as when patients come to believe that there is **a pill for every illness**. This may cause an apparent increased demand for drugs.

- Inefficiencies in supply, drug shortages, expired drugs, and availability of inappropriate drugs lead to a lack of confidence in the system by the prescriber and the patient.

2.17 9.7 Strategies to promote rational use of medicines

It is recommended that a combination of educational, managerial and regulatory strategies is used. The activities should be planned in such a way that they act to reinforce one another. Rules and regulations have little impact if target groups are not educated and informed and if management and supervision systems are not in place

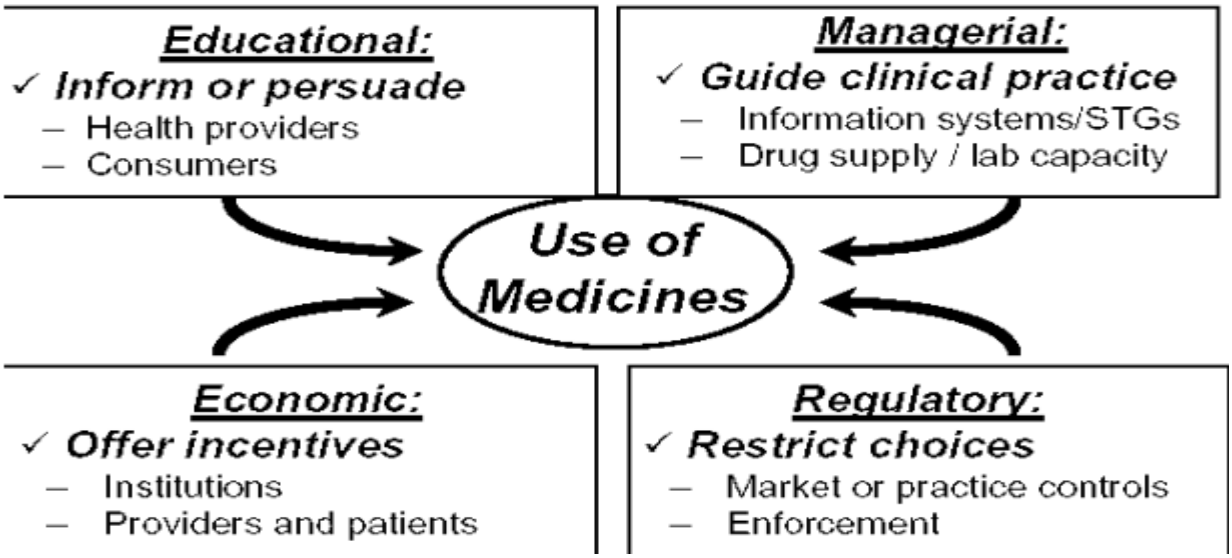

Fig: Strategies to promote rational use of medicines

Educational strategies: To Persuade

Rational use depends on the knowledge, attitudes and practices of health care practitioners and consumers.

1. Basic Training of Health Professionals

Emphasis is needed to be placed on problem-solving techniques, critical appraisal skills and good communication with patients. The essential drugs concept and its practical application should be included in the curriculum of all health workers.

2. In-service Training of Health workers

Continuing education, supervisory visits and focused lectures and workshops can be effective in increasing knowledge and changing behavior.

3. Drug information

An underlying factor in many aspects of irrational drug use is the lack of access to independent drug information. All prescribers should have access to standard treatment guidelines, the essential drugs list and a drug formulary.

4. Consumer Information and Education: is used to promote adherence to treatment , focus on the common patterns of irrational drug use by the public and health and drug education to the public using the media

Managerial Strategies: To Guide

1. Clinical Guidelines, drug formularies, Essential Drugs Lists and Dispensing Standards development and distribution to health professionals.

Clinical guidelines indicate the most cost-effective therapeutic approach, on the basis of valid clinical evidence. Their impact is greatest if the end-users (prescribers and, to a certain extent, patients) are closely involved in the development. Drug bulletins provide summarized, comparative, independent and up-to-date information on selected drugs, and often include information about the cost of treatment.

2. Drugs and Therapeutics Committee in hospitals

Implementing comprehensive and coordinated rational drug use strategies in hospitals. Developing and coordinating hospital policies related to pharmaceuticals (e.g. on the selection of standard treatments, hospital formularies and drug budgets). Perform drug utilization studies and prescription reviews, and develop educational strategies to improve drug use and management.

Regulatory Strategies: To Enforce

Regulatory strategies to promote rational use include

1. Evaluation of Drugs for Market Approval and Scheduling of drugs registered for marketing in the country, scheduling decisions about which drugs are available ―over-the-counter‖ to consumers and which are available ―on prescription only

2. Control of Drug Promotion activities

Regulations to control Drug promotion are vital in increasing rational drug use. Promotion should be in line with national health policies, and comply with national regulations and any existing voluntary standards.

2.18 9.8 Role of pharmacy personnel in promoting rational drug use

1. Promoting rational prescribing practices: Pharmacy personnel, as professionals and members of a health team, can play an indispensable role in the following activities of promoting rational drug prescribing. Participate in the provision of formal and continuing education with respect to rational drug use in line with basic and clinical pharmacology and therapeutics. Provide current and objective drug information to medical practitioners using the following source of information.

Printed educational materials such as drug news, periodicals etc, Drug list and formulary, Standard treatment guidelines/protocols, Graphic educational material such as diagnostic and treatment flow charts, common health problems.

2. Patient and community education: pharmacy personnel involved in drug dispensing should give health education to patients and community to promote rational drug use.

Patient education: With the use of resources and facilities of health institution patients to give health education on drugs/medicines, while patients are waiting for health service. Educate patients individually or in groups while dispensing drugs. Example: patient counseling service and educate patients by displaying posters on the walls of the health institutions/appropriate boards.

Community education: Community education can be given through; mass media such as radio, Tv, newspapers, magazines…, and mass gatherings.

Chapter 10. Monitoring and evaluation

Chapter Descriptions

This chapter introduces students with the concepts and basic terminologies of monitoring and evaluation which will be used through M&E activities. Also, the chapter introduces the purpose of monitoring and evaluation. It incorporates tools used to investigate supply chain practice and performance as well as rational medicine use.

Chapter objectives

Upon completion of this chapter, students will be able to:

- Define Monitoring and Evaluation

- ☑ Identify tools used to investigate supply chain practice and performance
- ☑ Identify tools applied to investigate medicine use practice and performance
- ☑ Discuss data collection methods in pharmaceutical monitoring and evaluation

2.19 10.1 Introduction to Monitoring and Evaluation

What is Monitoring and Evaluation?

Monitoring and Evaluation is a process of continued gathering of information and its analysis, in order to determine whether progress is being made towards pre-specified goals and objectives, and highlight whether there are any unintended (positive or negative) effects from a project/program and its activities.

Monitoring is a continuous process of collecting, analyzing, documenting, and reporting information on progress to achieve set project objectives. It helps identify trends and patterns, adapt strategies and inform decisions for project or program management. It reviews in a continuous basis, the degree to which program activities are completed and performance targets or milestones are being met, focuses on tracking program inputs such as funding, staff, facilities, supplies, and training. It is part of the operational management of a program. It tracks outputs such as availability of medicines and supplies, number or percentage of trained staff, and quality of services. Systematic monitoring of inputs and outputs can help identify potential problems and corrective actions to be taken during program implementation.

Monitoring is sometimes referred to as process evaluation because it focuses on the implementation process and asks key questions: how well has the program been implemented? How much does implementation vary from site to site? Did the program benefit the intended people? At what cost?

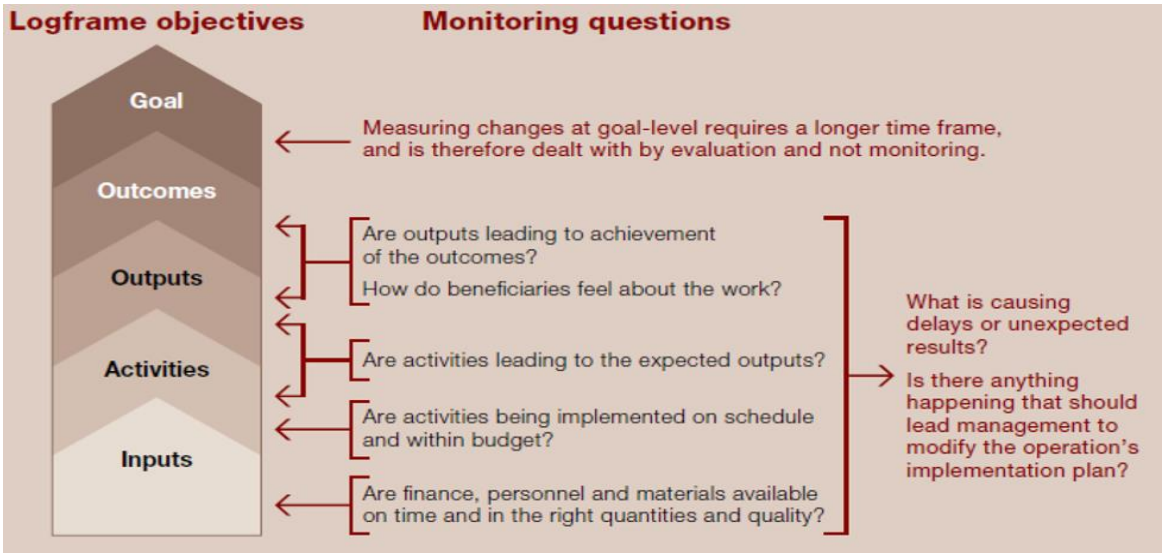
Logframe objectives
Monitoring questions
Goal
Outcomes
Outputs
Activities
Inputs
Measuring changes at goal-level requires a longer time frame, and is therefore dealt with by evaluation and not monitoring.
Are outputs leading to achievement of the outcomes?
How do beneficiaries feel about the work?
Are activities leading to the expected outputs?
Are activities being implemented on schedule and within budget?
Are finance, personnel and materials available on time and in the right quantities and quality?
What is causing delays or unexpected results?
Is there anything happening that should lead management to modify the operation's implementation plan?

Figure: Monitoring and Logframe

Evaluation is a periodic assessment, as systematic and objective as possible, of an on-going or completed project, programme or policy, its design, implementation and results. It involves gathering, analyzing, interpreting and reporting information based on credible data. The aim is to determine the relevance and fulfillment of objectives, developmental efficiency, effectiveness, impact and sustainability. It analyzes progress toward meeting established objectives, goals, or results. It provides feedback on the outcomes of activities, such as changes in prescribing behavior and health care-seeking behavior, whether plans have been met, and the reasons for success or failure, and direction for future programmatic plans. Evaluation methods may be used to carry out a situation analysis or a needs assessment as the first step in designing an appropriate intervention to improve program performance. Evaluation takes a longer-term perspective and concentrates on the strengths and weaknesses of the program strategies. Evaluation is sometimes referred to as "impact evaluation" ; because it asks and measures how well the program activities have met expected objectives and/or the extent to which changes in outcomes can be attributed to the program or intervention. The difference in the outcome of interest between having or not having the program or intervention.

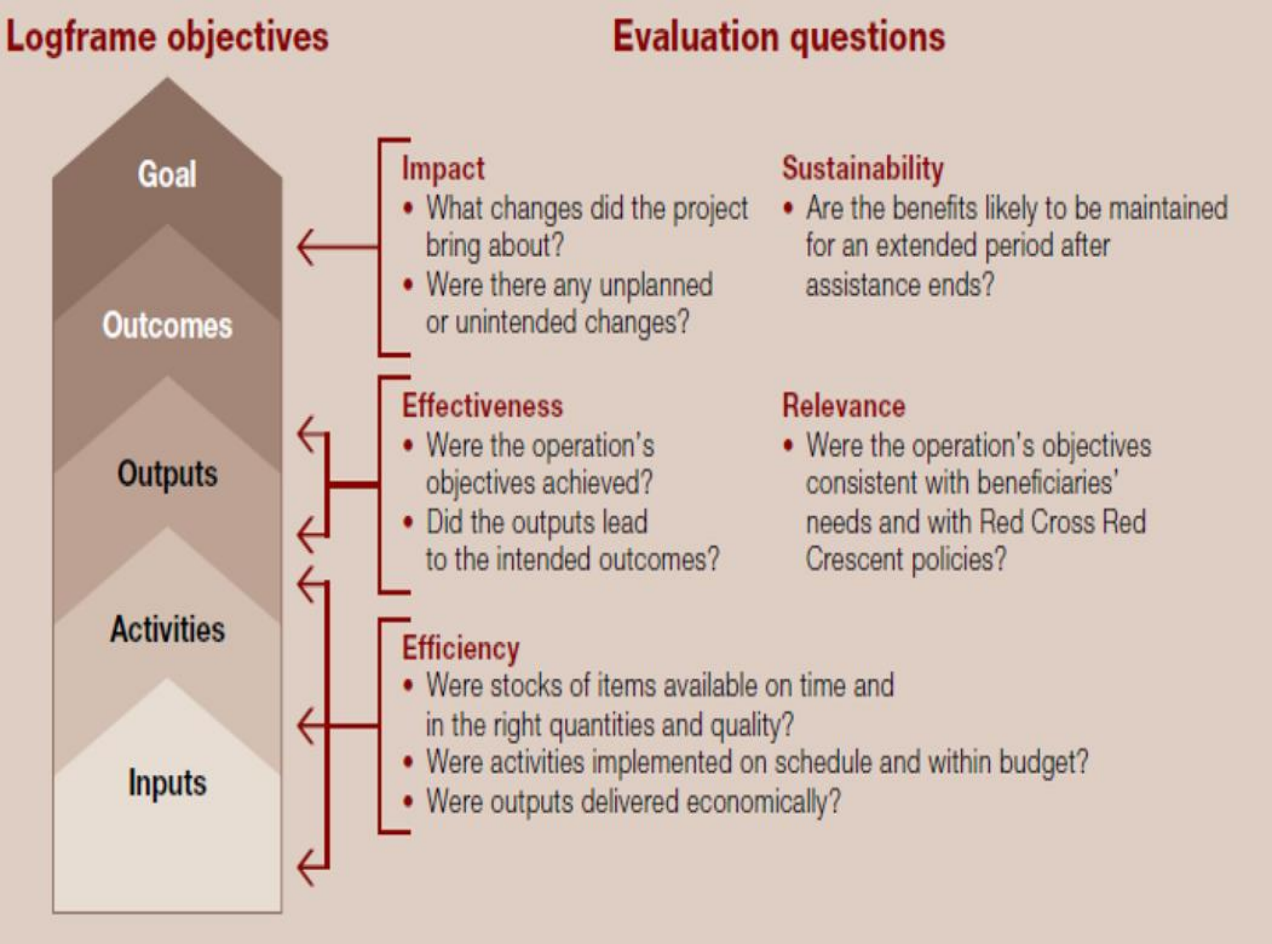
Logframe objectives
Evaluation questions
Goal
Outcomes
Outputs
Activities
Inputs
Impact
• What changes did the project bring about?
• Were there any unplanned or unintended changes?
Sustainability
• Are the benefits likely to be maintained for an extended period after assistance ends?
Effectiveness
• Were the operation's objectives achieved?
• Did the outputs lead to the intended outcomes?
Relevance
• Were the operation's objectives consistent with beneficiaries' needs and with Red Cross Red Crescent policies?
Efficiency
• Were stocks of items available on time and in the right quantities and quality?
• Were activities implemented on schedule and within budget?
• Were outputs delivered economically?

Figure: Evaluation and Log frame

The difference between monitoring and evaluation is described as

Monitoring: Is an ongoing, continuous process. It compares planned activities against achievements and is used to determine if activities need adjustment during the intervention to improve desired outcomes. It requires collection of data at multiple points throughout the program cycle, including at the beginning to provide a baseline.

Evaluation is Periodic assessment which compare standards against achievements and informs future programming for all stakeholders

2.20 10.2 Purpose of Monitoring and Evaluation

Timely and reliable M&E provides information to support project/programmed implementation with accurate, evidence-based reporting that informs management and decision-making to guide and improve

project/programmed performance, contribute to organizational learning and knowledge sharing by reflecting upon and sharing experiences and lessons, uphold accountability and compliance by demonstrating whether or not our work has been carried out as agreed and in compliance with established standards and with any other stakeholder requirements, provide opportunities for stakeholder feedback, Promote and celebrate project/program work by highlighting accomplishments and achievements, building morale and contributing to resource mobilization, strategic management in the provision of information to inform setting and adjustment of objectives and strategies and build the capacity, self-reliance and confidence of stakeholders, especially beneficiaries and implementing staff and partners to effectively initiate and implement development initiatives.

2.21 10.3 Characteristics of monitoring and evaluation

Monitoring tracks changes in program performance or key outcomes over time. It has the following characteristics: conducted continuously, keeps track and maintains oversight, documents and analyzes progress against planned program activities, focuses on program inputs, activities and outputs, looks at processes of program implementation, considers program results at output level, considers continued relevance of program activities to resolving the health problem, reports on program activities that have been implemented, and reports on immediate results that have been achieved

Evaluation is a systematic approach to attribute changes in specific outcomes to program activities. It has the following characteristics: conducted at important program milestones, provides in-depth analysis, compares planned with actual achievements, looks at processes used to achieve results, considers results at outcome level and in relation to cost, considers overall relevance of program activities for resolving health problems, references implemented activities, reports on how and why results were achieved, contributes to building theories and models for change and attributes program inputs and outputs to observed changes in program outcomes and/or impact

2.22 10.4 Monitoring Methods

How are monitoring activities organized, and where does monitoring information come from?

Information required for monitoring can be obtained through a combination of four formal and informal methods.

1. Supervisory visits: Support the performance of individual staff or health care workers, provide some on-site, in-service training, and represent an important method for informal but direct monitoring of program implementation should reinforce routine reporting requirements. Such visits may include; checking the quality of entries on standard reporting forms, such as inventory management forms (for example, stock cards), sometimes collection of information, such as the availability of specific medicines, for special studies.

2. Routine reporting

The core of a monitoring system for pharmaceutical supply programs is accomplished through the PMIS. A PMIS consists of; record-keeping documents; data reporting forms; feedback reports; and procedures that govern the availability, use, and flow of information up and down the system, including tracking the availability and use of medicines. Depending on the program's objectives, routine reporting focuses on the; availability of supplies at different levels in the system, finances, procurement and supplier performance, training, quality assurance, and medicine use, clear presentation of reported information, feedback to those providing the information, and follow-up action contribute to the effectiveness and usefulness of the reporting system. Reports should include; both quantitative information and brief descriptions of processes, key problems, and proposed follow-up actions.

The biggest failures in routine reporting systems are— Overdesign and Under implementation, collecting too much data usually results in too little analysis and reporting systems that are overly complex result in poor compliance with reporting requirements.

The content of routine reporting systems should be limited to the minimum amount of information that the typical reporting unit can reasonably be expected to provide and that can routinely be analyzed for decision making and feedback purposes. Identification of key data requirements is the result of a prioritization exercise that considers the critical information needs of all components of the pharmaceutical supply cycle.

▼ the simple rule is: do not collect what you cannot use.

3. Sentinel reporting systems

A sentinel reporting system consists of a carefully selected sample of health facilities or dispensaries that are given greater recording and reporting responsibilities. common in disease control programs such as HI V/AIDS prevention, control of diarrheal disease, and treatment of sexually transmitted diseases. useful to supplement routine reporting,

Differs from routine reporting in the amount of information collected, the frequency or promptness of report submission, and the level of accuracy demanded.

Sentinel sites provide a relatively economical means of collecting up-to-date, and detailed information on disease incidence, antimicrobial resistance, and responses to program interventions.

Need for sentinel reporting. A sentinel reporting system is most useful when a system is undergoing rapid or substantial change, such as when a new treatment or public health intervention is being introduced. Differs from routine reporting in the amount of information collected, the frequency or

promptness of report submission, and the level of accuracy demanded. Sentinel reporting helps assess the implementation and short-term effect of changes or interventions such as— Introduction of a major new computerized stock management system, transition from a central medical stores system to a decentralized system, introduction or scale-up of a treatment program, such as ART, routine reporting system answers only the questions it asks, a sentinel reporting system can be useful to detect unexpected or unintended outcomes.

Selection of sentinel sites: The level and number of health units in a sentinel system depend on the organization of the health and pharmaceutical management systems, the monitoring objectives, and the overall diversity within the country. Generally, at least six units should be included within each level. Selection of specific districts, locations within districts, or health facilities is generally purposeful, not random. Selection is aimed at achieving diversity rather than statistical representativeness

4. Special studies

Sometimes managers and planners need to gather information that is not available from routine or sentinel reporting. Examples of topics that may warrant a special study include—Names, dosage forms, and values of medicines purchased by individual health units, names, dosage forms, and value of recently expired medicines, reasons for expiry of pharmaceuticals, average percentage of essential medicines available, level of patient adherence to prescribed treatment, level of prescriber adherence to standard treatment protocols.

2.23 10. 5 Designing the Monitoring System

The principles for designing a monitoring system are to- focus on key monitoring questions and indicators; keep data collection to a minimum; develop practical procedures for managing monitoring information; and should consider the need to make comparisons between performance of similar programs, performance of different facilities within the program, and performance over time. Design should also consider how information will be available for timely feedback and follow-up action.

The «KISS" concept should be applied: keep it simple and straightforward (or keep it short and simple).

1. Create and follow a clear coding guide
2. Avoid using multiple third-party tools
3. Streamline (well-define) the review process.

Initial monitoring efforts can focus on issues of selection and procurement. Medical stores data, for example, are often easy to collect. As the program develops, the monitoring system and core indicators can be expanded to cover medicine distribution and use. Regardless of the approach taken, the design of the monitoring system

must be based on a sound understanding of how the system works, including the relationships between system inputs, outputs, and desired outcomes.

When a facility is introducing or phasing in a new activity, practice, or program, it can be matched to a control site that has not yet been introduced to the new practice or program. The control site should be as similar to the program site as possible, so that any changes can be more reliably attributed to the new program. If no control site is available to use as a comparison, baseline data can be collected to use as a basis for assessing development after the program is started at the site. If more than one facility is initiating a program, the different facilities can serve as comparison groups to monitor how well each group is progressing.

2.24 10.6 Evaluation

Depending on the timing and purpose, evaluations may be of three types

- Needs assessment (situation analysis)
- Formative evaluation (midterm review)
- Summative evaluation (final evaluation)

A needs assessment or situation analysis is meant to appraise the pharmaceutical system or essential medicines program and to identify areas of strength and weakness. The purpose is to design a project to address major weaknesses in the system.

Formative and summative evaluations are more programmatic and concerned with answering some or all of the following questions;

Is the program relevant? Are its goals and objectives appropriate to the present circumstances of the country in the pharmaceutical system? Is the program effective? Is it achieving satisfactory progress toward its stated goals and objectives? What are the reasons for success or failure? Are monitoring results representative? Do the results from the program's monitoring system reflect the actual situation? Is the program efficient? Are the effects of the program being achieved at an acceptable cost compared with alternative approaches to providing the same services? Is the program sustainable? Financially and institutionally, can the program continue with present levels of local inputs? If external financial and technical assistance is involved, can the program continue after it has stopped? Is the program having the intended impact? Does the program appear to be achieving or will it achieve its intended long-term health care benefits?

What future changes should be made? What recommendations can be made for program development, new plans or project assistance? Are new goals or objectives needed?

10.6.1 Conducting Evaluation

The three approaches to assessment are self-assessment, limited assessment, and structured assessment.

Structured assessment: is the most comprehensive but requires the most resources. The choice of assessment approach depends on available financial and human resources, timing, sponsorship, and intended uses of the results. Health program and health project evaluations are sometimes limited assessments which consist primarily of interviews, secondary analysis of existing monitoring and other data, and review of available documents. Evaluations are expected to contain performance data indicating what services and outcomes are resulting from the program. The starting point for an evaluation should be the data collected through the monitoring system, but field surveys using standard pharmaceutical sector assessment indicators will contribute to a much more objective, credible, and useful evaluation. Evaluation is much like a research project.

Who should evaluate?

When individuals involved in a program carry out an evaluation; they have the advantage of understanding its aims and design and such evaluations can be subjective and may miss important lessons. Therefore, outsiders are frequently asked to perform evaluations. Because they are disinterested, outsiders may be more objective and may bring fresh ideas.

Outside evaluators might come from local universities, local non-governmental organizations, international organizations, or organizations in other countries.

Resources required

Evaluation is an activity that goes beyond routine monitoring and requires staff, time and funds to be earmarked for it.

Some key considerations for the budget include; Planning time (technical lead and administrative/logistics support), Team member time (preparatory fieldwork, and report preparation), Travel costs (as needed), Airfare, Per diem, Telecommunications costs (phone/Internet access), Contracted services (as needed), Local consultant and translator(s), Driver(s) and car(s), Conference room facilities for the stakeholder workshop (room charges food costs, and equipment rental), Miscellaneous charges and photocopies—reference materials, reports, etc. Postage (mailing documents prior to visit, for example)

2.25 10.7 Using Indicators for Monitoring and Evaluation

Indicators: An indicator is defined as a quantitative measurement of an objective to be achieved, a resource mobilized, an output accomplished, an effect obtained or a context variable (economic, social or environmental).

Indicators are variables that measure change. precise information needed to assess whether intended changes have occurred. Indicators can be either quantitative (numeric) or qualitative (descriptive observations). may also be expressed as binomials such as “yes” and “no’

10.7.1 Applications of indicators

When used to make measurements at one point in time, indicators allow a manager:

➾ to compare a program’s performance with a target level of performance (or with another program’s performance) and to identify areas of relative strength and weakness.

Applied over time, such indicators can be used to set and monitor performance improvement targets, such as; Monitoring implementation of program plans and work plans, Evaluating achievement of long-term goals, assessing the performance of individual units, Identifying relative strengths and weaknesses in current policies and system, measuring the effect of new policies or management systems, self-monitoring to improve performance, demonstrating needs to treasury, donors, or other funders and reporting on progress to senior officials, donors, or other interested parties. Pharmaceutical supply system managers can identify input, process, output, outcome and impact measures for each major component of the pharmaceutical supply cycle. Managers of pharmaceutical supply systems will note that many of their management activities focus on- inputs such as financing, human resources, and the existence of policies and standard operating procedures.

Definition of some terminologies

inputs – the resources invested in a program, for example, technical assistance, computers, vaccines, condoms or training; e.g.; developing clinical training curriculum.

processes – the activities carried out to achieve the program’s objectives; e.g.; conducting training events

outputs – the immediate results achieved at the program level through the execution of activities; e.g.; practitioners trained in new clinical techniques.

outcomes – the set of short-term or intermediate results at the population level achieved by the program through the execution of activities; e.g.; increase in clients served by (newly) trained providers.

impacts – the long-term effects, or end results, of the program, for example, changes in health status; e.g.; declining morbidity level in target population, the influence of pharmaceutical programs on mortality, morbidity, fertility, etc.

10.7.2 Characteristics of Good indicators

A SMART

Specific(S): focused and clear. The performance target is dearly written to avoid different interpretations

Measurable (M): quantifiable and reflecting change. The target allows a team to monitor and evaluate progress toward achieving its result.

Attainable (A): reasonable in scope and achievable within set time-frame. It is in line with the scope of a team's program or work activities, so that it can have influence or make changes.

Relevant (R): pertinent to the review of performance and the target is achievable within the time allowed.

Time-bound/Trackable (T): progress can be charted chronologically. The performance target has a specific time period for complexion.

Also be **CREAM**: **C**lear, **R**elevant, **E**conomical, **A**dequate and **M**onitor-able

Selecting indicators

In selecting indicators, carefully consider how data will be collected is also important and the sources and the cost of collecting and processing data.

Five necessary criteria for selecting appropriate performance indicators are—

Clarity: the indicator is easily understood and calculated

Usefulness: the indicator reflects an important aspect of performance.

Measurability: the indicator can be defined in quantitative terms and used within existing constraints on information quality and availability,

Reliability: the indicator permits consistent assessment over time and among different observers.

Validity: the indicator is a true measure of what it is meant to measure

Indicators; may be routinely available from standard recording and reporting systems (such as percentage of indicator pharmaceuticals available), require a special survey (for example, percentage of pharmaceutical costs covered by user fees or percentage of health units using stock cards correctly), (some) represent annual summary measures (per capita government pharmaceutical expenditure or percentage by total value of pharmaceuticals purchased through competitive tender)**.**

Some common pitfalls of monitoring and evaluation

Although monitoring and evaluation are two distinct activities, they share certain common pitfalls;

Failure to identify the basic questions: All monitoring and evaluation activities should start with a clear statement of the questions they intend to answer. Without this, the information gathering has no focus.

Over ambitiousness: Collecting too much information is perhaps the most common failing. A basic rule is that more information means greater expense, less accuracy, more time spent managing the data, less time spent interpreting the data and providing feedback, and less time for using the data.

Complexity: Monitoring systems should be as practical and streamlined as possible. Cumbersome systems have often been designed from the top down, with insufficient testing and input from staff involved in generating and using monitoring information.

Lack of integration with planning and implementation: Monitoring and evaluation activities should follow directly from program plans, link closely with ongoing implementation activities, and lead logically into the next round planning.

Failure to build on existing systems: Existing information systems are never perfect, but considerable resources can be squandered trying to build a separate system instead of building on and strengthening existing systems.

Inadequate resources: Both monitoring and evaluation require considerable financial and human resources. It is generally better to seek additional resources or narrow the scope of assessment rather than try to gather too much information with too few resources.

Luck of objectivity: Management Indicators introduce some objectivity into the assessment process; assessments based only on subjective information are less credible and less useful.

Jumping to wrong conclusions: Well-designed monitoring and evaluation systems allow some cross-checking of findings. Taken out of context, individual monitoring reports and evaluation observations can be misleading.

Lack of comparison data: Observations must be compared overtime, against agreed-upon performance standards, among health units at the same level, or across countries. Good baseline data against which changes can be compared are especially useful, but to be valid, they must come from the same sources and have the same measures as the follow-up data, if the sources or measures are altered, it is difficult to say whether apparent changes (good or bad) are real or are a result of the assessment process.

2.26 10.8 Tools to investigate supply chain practice and performance

Pharmaceutical supply chain practice and performance monitoring is an integral part of any health supply/ logistics system because it can describe the performance of the supply system and point to areas that need

improvement. Monitoring and evaluation also allow for accountability so that all stakeholders can know the impact of their work and investments; it also allows for advocacy as it can highlight program successes and areas of greatest need.

10.8.1 Supply chain practice and performance measures

Supply chain practice and performance measures are the numbers and ratios a company tracks to measure how efficiently it delivers goods to customers. Keys to efficiency in supply chain execution include how well and cost-effectively companies drive the flow of materials from procurement to delivery, including activities like production, warehousing and transportation. Supply chains are fluid and are continuously adjusting to changes in supply and demand for the products they handle. To get the performance desired from supply chains requires a company to monitor and control its operations on a daily basis.

There are four performance measure categories in supply chain management practice. which are measured objectively, specific, and high-level measures recommended to be used to determine achieving excellence in the supply chain. Customer service (measures the ability of the supply chain to meet the expectations of its customers), internal efficiency (ability of a company or a supply chain to use its assets as efficiently as possible), demand flexibility (the ability to respond to uncertainty in the range of products and to act quickly), and product development (a supply chain's ability to continue to evolve along with the markets it serves) performance measures /metrics further quantified or explained by key performance indicators.

What are supply chain KPIs? Supply chain key performance indicators (KPIs) quantify how well a supply chain is performing. Leaders need to decide which KPIs are most important to track. Because there are many metrics that can add value, it is often advisable for companies to divide supply chain KPIs into tiers based on functions. A facility/company may decide on a bucket of metrics that are most important to its business.

1. **Upside supply chain flexibility:** upside and downside refer to the direction of supply demand change. A demand increase means upside, a decrease means downside. Upside SCF is defined as the number of days required to achieve an unplanned sustainable 20% increase in quantities delivered.
2. **Upside Supply Chain Adaptability:** is defined as the percentage of increased production quantity that a company can achieve and sustain in 30 days.
3. **Downside Supply Chain Adaptability**: Downside Supply Chain Adaptability is defined as the percentage of quantities that are sustainably reduced compared to the standard quantity with 30 days' reaction time not having extra inventory or causing cost penalties.

4. **Perfect order fulfillment:** is defined as the percentage of orders delivered to the right place, with the right product, at the right time, in the right condition, in the right package, in the right quantity, with the right documentation, to the right customer, with the correct invoice. Failure to meet any of these conditions results in a less than perfect order. If the order is perfect, it will reduce waste and keep good quality in a construction project. High KPI parameters indicate success.

   perfect=Correct item, Quantities match the order, Delivery meets committed date, Documentation is accurate and complete, Product is not damaged and performs as per specifications.

5. **Supply chain management cost:** Cost control is one of the key factors ensuring financial efficiency. Cost reduction is one of the most frequently mentioned goals in supply chain management.
6. **Return on working capital:** This KPI will help suppliers to know the return of working capital and profit. So, it can be used to measure the supplier activities in the supply chain. The KPI successful parameter is higher is better.
7. **Return on a supply chain fixed asset:** Not all production activities must rent or buy the tools. But if the supplier can buy tools for production, it will be more beneficial for the next project or production. The KPI successful parameter is higher is better.
8. **Cash-to-cash cycle time: This metric tells you the length of time between when you pay suppliers for materials and when customers pay for the final finished product.**
9. **Cost of goods sold (COGS): The cost of goods sold, or COGS, refers to any direct cost associated with the production of a product. This includes materials, direct labor, machinery, and manufacturing overhead.**
10. **Customer order cycle time**: **Also known as order fulfillment cycle time;** Customer order cycle time tracks the number of days between your company receiving a purchase order and completing customer delivery.

2.27 10.9 Tools to investigate medicine use practice and performance

10.9.1 WHO Medicine/Drug Use Indicators

WHO drug use indicators are intended to measure aspects of health provider behavior in primary health-care facilities in a reliable way, irrespective of who collects the data. The indicators provide information

to health-care managers concerning medicines, prescribing habits and important aspects of patient care. All the indicators have been extensively field-tested in many countries and found to be relevant, easily generated, measured, valid, consistent, reliable, representative, sensitive to change, understandable, and action oriented.

The standardized drug use indicators were developed jointly by WHO and International Network for Rational Use of Drugs (INRUD) after a study conducted in many countries (WHO, 1993). These indicators are classified into two main classes.

1. Core Drug Use Indicators (12): These are highly standardized; they don't need national adaptation and they are recommended for inclusion in any drug/medicine use study.
2. Supplementary Drug Use Indicators (7): these are not standardized; they need national adaptation.

10.9.2 Core drug use indicators

Core drug use indicators are further classified into three:

A. Prescribing Indicators

1. Average number of drugs per encounter- Purpose: to measure the polypharmacy

Calculation: Average $Average = \frac{total\ number\ of\ drugs\ prescribed}{total\ number\ of\ encounters\ surveyed}$

Standard: optimal level $\leq$ 2 drugs per patient

2. Percentage of drugs prescribed by generic name

Purpose: to measure the tendency to prescribe by generic name

Calculation: $\% = \frac{number\ of\ drugs\ prescribed\ by\ generic\ name x 100\%}{total\ number\ of\ drugs\ prescribed}$, Standard: optimal level =100%

3. Percentage of Patients with an antibiotic prescribed

Purpose: to measure the overall level of use of antibiotics

Calculation: $\% = \frac{number\ of\ encounters\ with\ antibiotics\ prescribed x 100\%}{total\ number\ of\ encounters\ surveyed}$, Standard: Optimal level 30%

4. Percentage of drugs with an injection prescribed

Purpose: to measure the overall level of use of injections

Calculation:$\% = \frac{number\ of\ encounters\ with\ injection\ prescribed x 100\%}{total\ number\ of\ encounters\ surveyed}$, Standard: optimal level 10%

5. Percentage of drugs prescribed from EDL or formulary

Purpose: to measure the degree to which practices conformation national drug policy

Calculation: $\% = \frac{number\ of\ drugs\ prescribed\ from EDL, formulary\ or\ STG x 100\%}{total\ number\ of\ drugs\ prescribed}$

Standard: optimal level =100%

B. Patient Care Indicators

6. Average consultation time

Purpose: To measure the time that medical personnel spend with patients in the process of consultation and prescribing

Calculation: $average = \frac{total\ time\ for\ a\ serious\ of\ consultation}{total\ number\ of\ consultations}$, Standard: optimal level 10 minutes per patient

7. Average dispensing time

Purpose: To measure the average time that personnel dispensing drugs spend with patients.

Calculation: $\frac{total\ time\ for\ dispensing\ drugs\ to\ a\ serious\ of\ patients}{total\ number\ of\ encounters}$

Standard: Optimal level $\geq$ 60 seconds per patient

8. Percentage of drugs actually dispensed

Purpose: To measure the degree to which health facilities are able to provide the drugs which were prescribed.

Calculation:$\% = \frac{Total\ number\ of\ drugs\ actually\ dispensed x100\%}{total\ number\ of\ drugs\ prescribed}$, Standard: Optimal level =100%

9. Percentage of drugs adequately labeled

Purpose: To measure the degree to which dispensers record essential information on the drug packages they dispense

Calculation: $\% = \frac{Total\ number\ of\ drug\ packages\ W\ patient\ name,drug\ name\ and\ dosage\ regimen x100\%}{Total\ number\ of\ drug\ packages\ dispensed}$

Standard: Optimal level =100%

10. Patients' Knowledge of correct dose

Purpose: to measure the effectiveness of the information given to patients on the dosage schedule of the drugs they receive

Calculation: $\% = \frac{Total\ number\ of\ patients\ who\ can\ adequately\ report\ the\ dosage\ schedule\ x100\%}{Total\ number\ of\ patients\ interviewed}$

Standard: Optimal level =100%

C. Health Facility Indicators

11. Availability of copy of EDL, Formulary or STG

Purpose: To indicate the extent to which copies of the national EDL, local formulary or STG are available at health facilities.

Calculation: $\% = \frac{Number\ of\ health\ facilities\ having\ the\ copy\ X100\%}{total\ number\ of\ health\ facilities\ surveyed}$, Standard: Optimal level =100%

12. Availability Key Drugs

Purpose: To measure the availability at health facilities of key drugs recommended for the treatment of some common health problems

Calculation: $\frac{Number\ of\ available\ key\ drugs\ in\ the\ stock\ x100\%}{total\ number\ of\ drugs\ in\ the\ checklist}$, Standard: Optimal level =100%

10.9.3 Supplementary drug use indicators

WHO/INRUD medicine use indicators with less standardization and less experience in actual use include:

1. % Of patients treated without medicines
2. % Average medicine cost per encounter
3. % Of medicine cost spent on antibiotics
4. % Of medicine cost spent on injections
5. % Of prescriptions in accordance with STG
6. % Of patients satisfied with care provided
7. % Of facilities with access to impartial drug information

2.28 10.10 Data Collection methods

It is impossible to address all aspects of use for each individual drug, but it is important to limit data collection to only the most important and relevant aspects of drug use. Different types of drug use information are required depending upon the problem being examined. Aspects of drug use commonly surveyed are patient demographics, prescriber details, indications/contraindications, side/adverse effects, dosage information, drug or drug class duplication, drug interactions, monitoring of drug therapy patient instructions/deductions and cost of drug therapy

The basic methods of collecting data or information in a pharmaceutical care assessment are: -

- Document review
- Key informant interviews
- Collection of data from existing records.
- Prospective studies

Document review: Many countries have been conducting studies to narrate problems in the pharmaceutical sector and have made attempts to correct them. When donors have participated in improving pharmaceutical services, many relevant reports are likely to exist. Government agencies can provide budget reports and, in many cases, files of technical reports by various agencies in the pharmaceutical sector. A review of the literature should be one of the first steps in any assessment. Failure to include this important step inevitably results in a waste of time and money to regather data that are already available and reinvent analyses and recommendations that duplicate those already made.

Key Informant Interviews: Interviews are one of the quickest ways to learn about urgent problems, if the assessment team is able to identify the people who are most knowledgeable about the situation and if these people are prepared to discuss the situation frankly. Interviews may be misleading, however, if the informants are not fully frank because of fear of retribution or if they have some vested interest in hiding or distorting information.

Nevertheless, interviews are essential for insight into the political and administrative processes, which are major determinants of whether assessments will lead to real action. Interviews may be conducted with or without structure. In the unstructured format, the interviewer relies on personal experience to ask relevant questions and to ensure that interviewer should be knowledgeable and well trained. In the structured approach, the interviewer uses a written survey form listing the important questions and the qualitative and quantitative information to be solicited.

Data collection from retrospective record review

A record review is a critical step in all structured assessments and should be done at each site where reasonably well-organized, complete, and current records exist. Where records are totally disorganized and badly out-of-date, the information gained may not be worth the effort, and other methods will be needed. Relevant records include government publications on budgets

and expenditures, drug regulatory inspection reports, patient medical records, pharmacy dispensing records, records of procurement and accounts payable to suppliers, warehouse ledgers, bin cards and computer records, and accounting and finance records. Private-sector records to review may include company financial reports, balance sheets, sales and stock data, and customs and import data.

Data collection by prospective field observation

When needed information cannot be obtained from a retrospective review of records, it may be possible to use prospective observation to obtain the information. For example, one method of reviewing prescribing practices in a health facility is to examine clinical charts and dispensing records. If these records are not available, the team can observe patient encounters directly and record the prescribing in that manner (a patient exit survey). Some types of data are best obtained by prospective methods. For example, to determine whether private pharmacies are selling prescription-only medicines without a

prescription, the best method is a simulated purchase survey, where local data collectors visit a sample of pharmacies and actually attempt to purchase prescription medicines.

Other methods for collecting data

Other common methods for obtaining useful data include focus groups and household surveys.

Source of data

A. Large databases

Efficient use of health care resources - computer databases or medical record sections, International, national or local- comparative studies can be planned at various levels. May be diagnosis linked or non-diagnosis linked, diagnosis linked data enable drug use to be analyzed according to patients' characteristics, therapeutic groups, diseases or conditions and clinical outcomes.

B. Data from drug regulatory agencies

Are repositories of data on which drugs have been registered for use, withdrawn or banned within a country? Agencies have the legal responsibility of ensuring the availability of safe, efficacious and good quality drugs. Possible to obtain data on the number of drugs registered in a country from such agencies. Importation data like product type (i.e., generic or branded), volume, port of origin, country of manufacture, batch number and expiry date may be collected.

C. Supplier (distribution data)

Drug importation, local manufacture, customs service, wholesalers, in countries where licenses are required from drug regulatory authorities before importation of drugs. Generally, be used to describe total quantities of a specific drug or drug group, origins of supplies and type (i.e., branded or generic), distribution at different levels of supplies can be compared.

D. Practice setting data

Generate indicators that provide information on prescribing habits and aspects of patient care. E.g.; Prescribing data, dispensing data, aggregate (facility) data, over-the-counter and pharmacist-prescribed drugs, telephone and internet prescribing

Chapter 11: PSCM Related Initiatives

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    - 1.2. Basic components of IPLS
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2. **APTS of Ethiopia**
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Chapter Description

This chapter aims to equip students with skills that enable them implement the national supply chain system (the integrated pharmaceutical logistics system): recording and reporting on stock levels and usage of pharmaceuticals, ordering pharmaceuticals, receiving and storing pharmaceuticals, issuing pharmaceuticals between and within facilities, as well as maintain adequate amount of pharmaceuticals. The chapter also aims at equipping the students with the knowledge and skills on the concept of APTS; how to perform transparent and accountable pharmaceutical transactions, provision of pharmaceutical services, as well as on how to conduct workload analysis, utilize medicines budget efficiently and producing data driven reliable information; at the end to contribute better health outcomes.

Chapter Objectives

Upon successful completion of this section, the students will be able to:

- Describe the flow of pharmaceuticals and information in the IPLS
- Identify the basic components of IPLS at health facility
- Describe the essential elements of APTS
- Manage pharmaceutical transactions and perform daily summary and monthly report
- Define health commodity security
- describe the key components of health commodity security framework

Ethiopian Integrated Pharmaceutical Logistic System (IPLS)

Introduction

The provision of complete health care necessitates the availability of safe, effective and affordable drugs and related supplies of the required quality, in adequate quantity at all times. Despite this fact, in the past, the pharmaceutical supply chain management system of the country had several problems including non-availability, unaffordability, poor storage and stock management and irrational use.

To solve these problems in public health facilities, Ethiopian Pharmaceuticals Fund and Supply Agency (EPFSA) was established based on the Pharmaceuticals Logistics Master Plan (PLMP). The Agency is mandated to avail affordable and quality pharmaceuticals sustainably to all public health facilities and ensure their rational use. So as to execute its mandate in the area of pharmaceuticals supply in an efficient and effective manner, integrated pharmaceuticals logistics system (IPLS) has been developed and implemented since 2010.

Integrated pharmaceuticals logistics system (IPLS) aims to ensure that patients always get pharmaceuticals they need. To be successful, the system must fulfill the six rights of supply chain management by ensuring the right products, in the right quantity, of the right quality, at the right place, at the right time and for the right cost.

The IPLS integrates the management of essential pharmaceuticals including the following pharmaceuticals that were used to be managed vertically: HIV/AIDS, Malaria, TB and Leprosy, EPI, MCH and purchased essential drugs. It is the primary mechanism through which all public health facilities obtain essential and vital pharmaceuticals. Products included on the National pharmaceuticals procurement List (NPPL) are supplied and managed through the IPLS.

Overview of Pharmaceuticals and Information flow in IPLS

Program pharmaceuticals are ordered every two months by hospitals and health centers and delivered by EPFSA to these facilities directly or indirectly. Direct delivery sites are facilities that receive program pharmaceuticals directly from EPFSA hubs whereas non-direct delivery sites are health centres that receive products from EPFSA hubs through Woreda Health Offices (WoHOs).

Health posts report to health centres monthly and collect pharmaceuticals from those health centres; the health centres use the data in the Health Post report to calculate consumption and re-supply quantities.

For revolving drug fund (RDF) pharmaceuticals, health centres and hospitals will complete RRF as per the facilities review period which can be every two months, every quarter or every six months and collect products from affiliated EPFSA branch.

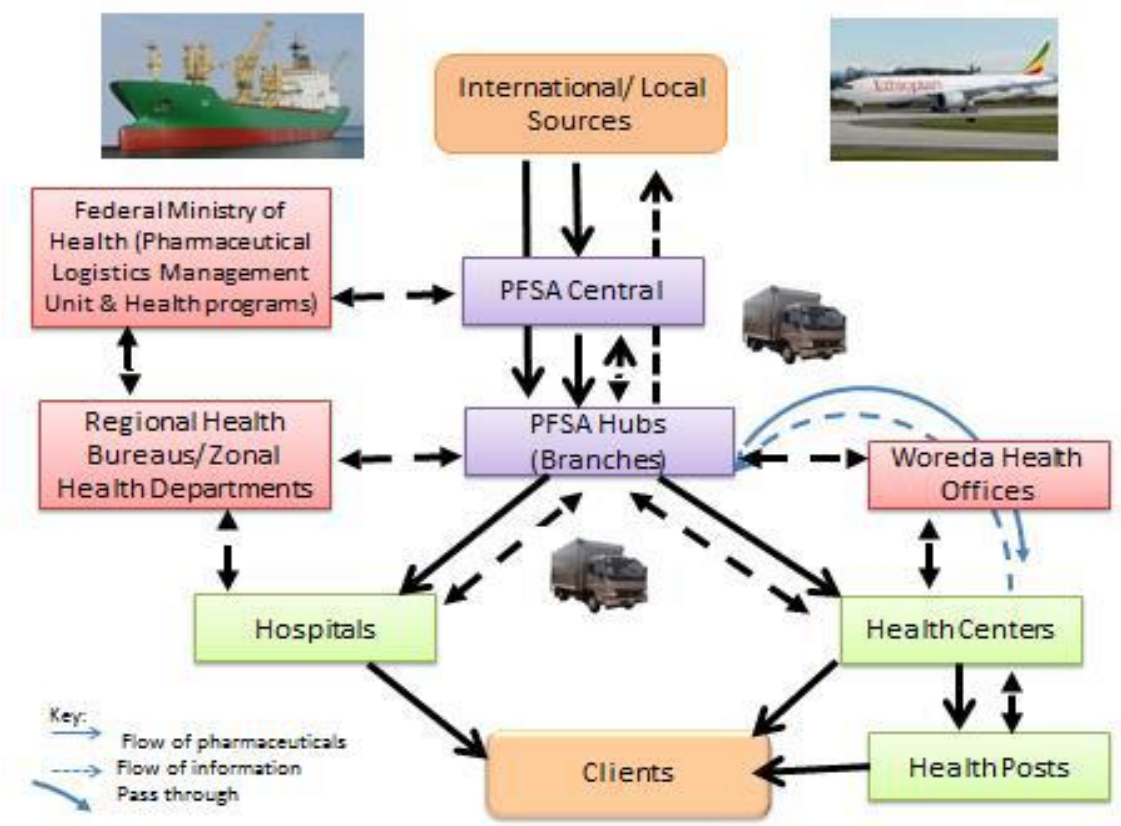


Figure 1. Flow of program pharmaceuticals and information in the IPLS

Logistics information is collected and reported monthly by health posts and every other month by health centres and hospitals on logistics management information system (LMIS) forms. For direct delivery facilities a combined report and requisition form is completed by health centres and hospitals and sent to EPSA Hubs for requisition processing; the health centre order includes the pharmaceuticals requirements of the health posts. For non-direct delivery facilities a combined report and requisition form is completed by health centres and sent to EpSA branches through WoHOs.

A copy of the health centre report and order and a copy of each health post report are sent to the Woreda Health Office for management and supervision purposes; a copy of the hospital report and order is sent to the Regional Health Bureau for management and supervision purposes.

The overall information system also includes a mechanism for providing feedback to lower-level facilities from upper-level facilities. In the feedback reports, facilities will be able to see how they are performing compared to other facilities in their area and will be able to facilitate stock transfer. For instance, the Woreda or EPFSA Hub may provide a short report to all of the health centres showing the stock status of priority products (vital pharmaceuticals), number of stock outs, reporting rate, and consumptions trend in the different health centres. The Woreda or EPFSA might also provide specific reports to health centres pointing out errors in their reports.

Basic Components of IPLS at Health Facility

IPLS at facility level includes the following basic logistics functions: inventory control system, logistics management information system (LMIS), and storage of pharmaceuticals.

Inventory Control System in IPLS

The purpose of an inventory control system is to inform personnel when and how much of a pharmaceutical to order and to maintain an appropriate stock level to meet the needs of patients. A well designed and well operated inventory control system helps to prevent shortages, oversupply, and expiry of pharmaceuticals.

To help maintain adequate stock levels, the *maximum months of stock, minimum months of stock* and an *emergency order point* have been established for each health facility in the system.

The inventory control system for the IPLS is a Forced Ordering Maximum/Minimum inventory control system. This means that all facilities are required to report on a fixed schedule (monthly at health posts, every other month at health centres and hospitals) for all products. In addition, all products are re-supplied each time a report is completed. In emergencies, an emergency order can be placed. In practice, this means that:

- Health centres and hospitals are required to report and order every two months.

- Health centres and hospitals calculate their own order quantities, ordering sufficient quantities of all pharmaceuticals to bring stock levels up to the maximum level.
- Health posts report data monthly to their affiliated Health Centre.
- The Health centre calculates the re-supply quantities that are needed to bring health post stocks up to the maximum level.
- If the stock on hand for any product at a facility falls below a set emergency order point before the end of the reporting period, an emergency order should be placed.

Standardized forms for inventory management

Internal Facility Report and Resupply Form (IFRR): The IFRR is used to report the internal transfer of items between the hospital pharmaceutical store and Dispensing Units. The IFRIR also calculates the quantity of each item that should be provided to the Dispensing Unit to reach maximum stock levels.

Report and Requisition Form (RRF): The RRF is used to order health commodities from PFSA. Orders should be placed every two months.

The quantity to be ordered is calculated as follows: Quantity requested = quantity issued from the store room in the previous reporting period x 2 minus stock on hand. All requisitions/orders shall carry a unique order number so that they can be official documents. If an order is placed to PFSA by telephone this should immediately be confirmed in writing.

Logistics Management Information System (LMIS) in IPLS.

The purpose of LMIS is to collect, organize, and report information to other levels in the system in order to make decisions that govern the logistics system and ensure that all six rights are fulfilled for each client.

The primary function of the LMIS is to support the management of essential pharmaceuticals.

Three essential data items are required to run a logistics system and, therefore, must be captured by the LMIS. These three essential data items are: stock on hand, consumption data, and losses/adjustments.

There are only three activities that happen to pharmaceuticals within a logistics system: they are stored, moved between facilities, and used to provide health services to patients. A well-designed logistics management information system will include records and forms that collect and report the three essential data items as they relate to these three activities.

Recording System in IPLS

Bin Cards and Stock Record Cards are used to account for products held in storage, including their receipt and issue. In the IPLS valuable information used to make re-supply decisions is recorded on the Bin Card and Stock Record Card; data from these records are used in reporting, calculating reorder quantities and for monitoring stock levels.

Reporting and Ordering Pharmaceuticals

Health facilities use the Report and Requisition Form (RRF) to:

- report on the quantities of pharmaceuticals used, lost or transferred, and the quantities of stock available
- order pharmaceuticals

Receiving pharmaceuticals from EPFSA

EPFSA delivers pharmaceuticals to health facilities which have submitted a completed and approved ERRF on time. Health facilities receive pharmaceuticals every other month. At the time of delivery, EPFSA trucks will wait while products are counted and verified, to take note of any discrepancies, to obtain proof of delivery (Model 19), to collect signed and sealed EPFSA delivery for the pharmaceuticals shipment.

Issuing Pharmaceuticals

When pharmaceuticals are issued from the storeroom to dispensing unit, the dispensing unit staff will provide essential logistics data on the Internal Facility Report and Resupply Form (IFRR). After completing the report section of the form, the health worker will take the IFRR to the store to obtain the needed pharmaceuticals. The store manager will use the information in the report section to determine re-supply quantities and issue the pharmaceuticals.

After issuing the pharmaceuticals, pharmacy store manager updates the Bin Card and the pharmacy head updates the Stock Record Card and files the IFRR.

Auditable Pharmaceutical Transactions and Services

Introduction

APTS is a data driven package of interventions designed to establish accountable, transparent and responsible pharmacy practice. It enables health facilities to optimize utilization of medicines budget, improve access to medicines, and decrease wastages. APTS continuously monitors the number, mix & performance of pharmacy workforce. It also improves pharmacy premise design and workflow. Through improving recording and documentation, it generates reliable and consistent information for decision making. As a result, APTS improves overall quality of pharmacy services thereby increasing patient knowledge and satisfaction. Ultimately it contributes to better health outcomes.

Key components of APTS

APTS has five result areas: efficient budget utilization, transparent and accountable transactions, reliable information, effective workforce development and deployment, and improved customer satisfactions. In

order to achieve these results, hospitals are expected implement selected interventions.

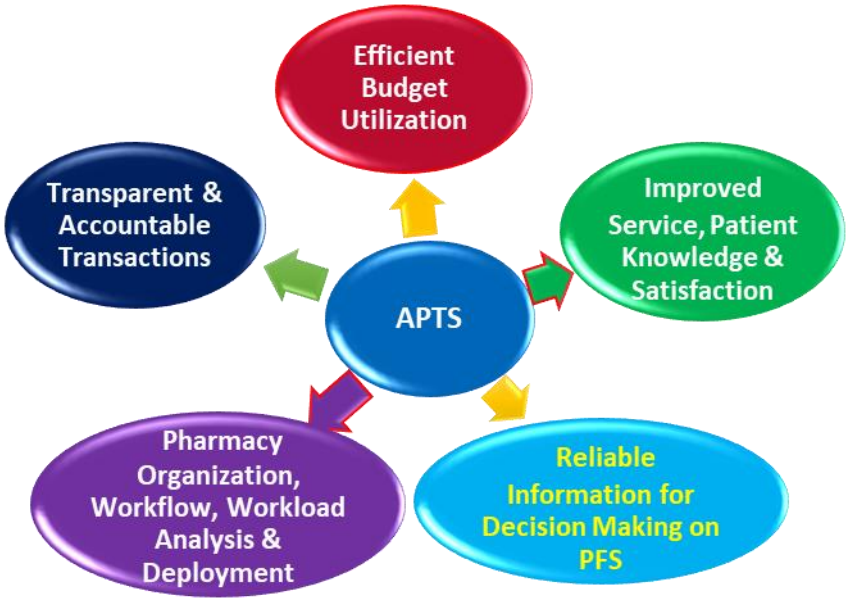

Efficient Budget Utilization
Transparent & Accountable Transactions
Improved Service, Patient Knowledge & Satisfaction
APTS
Pharmacy Organization, Workflow, Workload Analysis & Deployment
Reliable Information for Decision Making on PFS

Figure. Essential elements APTS (PFS ➔product, finance and service)

1. **Efficient Budget Utilization**

Activities to achieve this key result area of APTS:

- ► Identify top disease of the catchment area and select product
- ► Use updated facility specific medicine list reconciled by ABC-VEN
- ► Regularly do stock status & consumption to stock analysis
- ► Resource sharing and stock transfer
- ► Establish effective mechanisms to manage sales of medicines
- ► Finally, to reduce wastage rate and to improve availability

2. Transparent & Accountable Transactions

Activities to achieve this key result area of APTS:

- ► Establishing a legal framework (APTS Regulations ➔directives ➔guidelines): ➔Due to that APTS is enacted by regulation, directive and guideline in all regional states of Ethiopia. In addition, it is one of the priority agenda of the MOH and RHBS
- ► Use standard financial vouchers, (Model 19/22/health, sales tickets; Price control sheet developed by Bin owners and Model 20/Health (IFRR)
- ► Record all pharmaceutical transactions
- ► Record full description of pharmaceuticals
- ► Daily reconcile cost of medication sold
- ► Establish individual accountability by implementing bin management at all dispensing units
- ► Apply collective responsibility to ensure participatory effort in managing medicines and transactions
- ► Conduct regular audit and stop stealing specially some dangerous medicines like **antimalaria**
- ► Implementation of unique identifiers (coding) for all medicines, supplies and reagents using the coded master list of Ethiopia

3. Effective work force development and deployment

Activities to achieve this key result area of APTS:

- ► Total number of patients served per month should be calculated and fulfilling workforce needs based on the workload analysis by referring HSTG and enacted Article 26.6 of Federal APTS regulation.
- ► Provide all relevant in-service trainings including APTS for pharmacy and finance professionals
- ► Integrate APTS principles in pre-service education
- ► Providing one stop shopping service (by entrance & exit doors)

4. Reliable information for decision making

Activities to achieve this key result area of APTS:

- ► Generate monthly financial reports in cash, credit and for free
- ► Generate service report which indicates number of patients served per health facility & dispenser, per month, segregated by service type and unit
- ► Generate information on stock and consumption analyses, availability, and affordability of medicines
- ► Use reliable information (referring serial number of receiving, issuing and dispensing tools) for service and financial reports so that it can be used for decision-making
- ► Monitoring and evaluation results (M and E)

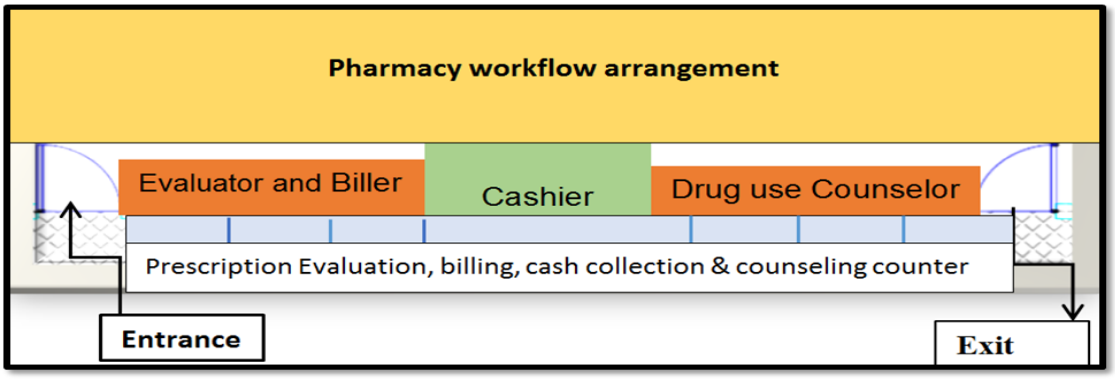
5. Improved customer satisfaction

Activities to achieve this key result area of APTS:

- ► Developing dispensary that is suitable for all types of patients like HIV/chronic patients that serve them separately (in counter where other person cannot not listen their counseling)
- ► Patient knowledge on correct dosage (Dose, frequency, duration, rout of administration)
- ► Improving availability of medicines
- ► Improving dispensing environment by using anthropometry and ergonomics principles to make it suitable
- ► Redesign the dispensing workflow: as Entrance door, dispensing process, Rx evaluator➔ cashier➔counselor) and exit door.
- ► The counseling counters should be separated for each customer, since their counseling should never be heard by others for customers like HIV patients
- ► According to majority of Ethiopians height, the best counter height for patient is 1.10m and for professional to give service being seated is 75cm.
- ► To make the counter suitable for mothers carrying children
- ► Providing quality pharmaceutical services

- Improve professionals' satisfaction
- Improve patients' satisfaction.

Pharmacy service organization



Patient Flow arrangement in APTS implementing health facilities

Inpatient pharmacies: should be situated near to each major ward to effectively monitor the use of pharmaceuticals in the respective wards.

OPD Pharmacy: may be organized in multiple locations so as to improve access and facilitate patient centered services

Emergency pharmacy: Since, the way of serving patients in emergency is different medicines may be dispensed by oral prescription and documented latter.

Drug Supply management unit: The overall operation of the unit should be coordinated by a dedicated pharmacist.

Drug Information service unit: This unit serves as a source of information to patients, health care providers and community.

Extemporaneous compounding: Health facility pharmacy should have compounding services with separate premises and equipped with the necessary facilities.

Clinical pharmacy service: Clinical pharmacy service should be provided in all pharmacy dispensing units.

Rooms for dispensaries

Within one dispensary the following rooms or cubicles should be available: -

• Mini-store or adequate storage sp • Prescription evaluation cubicles • Counselling cubicles • Special counselling	• Cashier cubicle • Pharmacy accountant office • Pharmacy coordinator office • Toilet, bathroom, dressing room/
Store Operations Separate store for: • Medicines and Supplies • Medical equipment • Separated Program and revolving drug fund (budget)	**Human Resource deployment should be based on the approved APTS regulation, and HSTG** pharmacies chapter • Pharmacy Services Director, Coordinators and others based on patient load analysis and stores

Infrastructure design for dispensaries in health facility

Patient Waiting Area

- The area should have adequate space with chairs.
- The area should have adequate lighting and ventilation.
- Adequate space shall be provided in front of each counter.

Counters and Cashier booth

- Evaluation and dispensing counters
- The number of counters should be sufficient to provide service.

- The counter should be 110cm height) Note: this size is the best for majority of Ethiopian

Cashier booth

- Access to cashier booth should be on the front side of counter.

Dispensary shelves

- It should have upper shelves and bottom cabinets.
- The distance between the dispensing shelves and casher booth should be sufficient.
- The maximum total height of shelve should not be more than 2 meters.

This room should have table with height of 0.72 to 0.75 cm and chair for both pharmacist and patients based on APTS principles

Shelfs and counter design based on APTS principles

Analysis of ABC/VEN reconciliation and interpretation of findings

ABC/VEN reconciliation involves categorizing the class of pharmaceuticals generated from ABC analysis by VEN to identify if there is relatively high expenditure on less priority pharmaceuticals.

Conducting ABC/VEN analysis by itself may not have importance. The findings should be interpreted and used for decision making.

For example from X health facility the following ABC-VEN reconciliation results obtained.

Stock Status Analysis (SSA)

Pharmaceutical stocks at the facility should be analyzed periodically after physical inventory is conducted every quarter, to see whether the stock is being sold or consumed at the expected levels. Stock status analysis is used to take actions before pharmaceuticals are expired or stocked out. The analysis allows evidence based decision making on utilization of current stock and future procurements. This process enables the health facility to minimize wastages and ensure effective and efficient utilization of budget and continuous availability of essential pharmaceuticals.

To conduct effective stock status analysis, the concept of maximum stock level, reorder level, minimum stock level, lead time, average monthly consumption, and safety stock (emergency order level) should be understood; refer to SOP manual for Integrated Pharmaceutical Logistic System.

Steps to conduct SSA

Step1: Identify pharmaceuticals that are candidates for the stock status analysis (SSA). Which pharmaceuticals are candidate?

- Those that fall in A category in the ABC analysis
- Those that fall in N-A category in ABC/VEN reconciliation
- Pharmaceuticals with near expiry regardless of its category
- Items recommended by experts (store managers, bin managers, others)

Step 2: Calculate average monthly consumption (AMC) of all pharmaceuticals subjected to SSA.

$$\text{AMC} = \frac{\text{Consumption of a Recent Quarter}}{3 - \text{Days out of stock (in months)}}$$

Note: For pharmaceuticals used for seasonal diseases (e.g malaria), it is advisable to take consumption data of the season in preceding years.

Step 3: Calculate the months of stock (MoS) for these pharmaceuticals. (MoS) is the number of months that can be covered by the stock at hand and add stock on order provided that the consumption pattern remains constant.

$$\text{Months of stock} = \frac{\text{Total stock on hand} + \text{pipe line qty}*}{\text{Average monthly consumption}}$$

Note: In situations where the monthly consumption is increasing with time, use last month's consumption instead of average monthly consumption.

This calculation is valid only when the remaining shelf life of the product is greater than the months of stock.

Step 4: Decide if the product is overstock, under stock

- **Over stock**: if the months of stock are more than 4 months, it is overstock. If the product is overstock, make sure that it can be consumed before expiry. If a pharmaceutical has short expiry date, the amount of stock that cannot be consumed until expiry is overstock.
- **Under stock:** If the months of stock are less than 2 months, it is said under stocked.

This may lead to stock out, so needs especial attention.

Actions to be taken after SSA

- **If over stock:**
  - Present to the management for decision making
  - Discuss with prescribers to identify any opportunity to use the pharmaceuticals
  - Reverse to the suppliers if possible
  - Transfer donate to other health facilities
- **If under stock: immediately refill the product.**
  - Determine additional stock needed to reach to the maximum (4 Months stock).

$$\text{Additional months of stock to reach max} = \frac{\text{Additional stock needed to reach max}}{\text{Average monthly consumption}}$$

Steps for Conducting Physical Inventory

Conducting physical inventory has three steps:

- Preparatory step (before)
- Actual physical count step (during)
- Analysis, interpretation, and reporting step (after actual inventory)

Step 1; The preparatory step (before actual physical count)

- Group all products per expiry dates, batch number, codes, unit, unit cost in the store and retail price in the dispensary units.
- Register and separate expired medicines
- Register medicines in the store and dispensaries in the 'before' parts of respective formats
  - Useable stocks: should be recorded in a separate physical inventory form
  - All damaged and expired stocks should also be recorded in another separate physical inventory form
  - Products with same generic names but with different expiry dates, cost or price and batches should be recorded in separate rows of the physical inventory form
  - All recorded items should be coded by each row. All medicines with different cost will have variable codes.
- Sign in the signature spaces and write name of the recorder
- An internal auditor will be available to mark and sign the cut off points on the vouchers, registers and sales tickets before taking physical inventory.
- Inform all pharmacy professionals working in the store and dispensaries about the physical inventory plan, so that everyone will avail themselves during physical inventory except those who are working at emergency pharmacy.

Actual physical counting step (during physical count)

Divide medicines by bin ownership and start inventory

Step 2. Activities in the second phase (during physical inventory): -

- ✓ The assigned professionals should be grouped into teams of two persons
- ✓ Every two personnel should be assigned in separate shelves

- ✓ The first person should count physically starting from bottom up as per the registered products serial number. The second person will record the quantity and both will sign on the space ‘counted-by’.
- ✓ Recount the already counted items by exchanging counting teams and sign on the signature space for ‘recounted-by’.
- ✓ If there is discrepancy, the team will inform to the first team and they will count the shelf for the third time together with the first team.
- ✓ Whenever, there is shortage or overage when compared with bin cards and stock cards, the responsible person should be communicated immediately and asked for justification for the discrepancy. Once the responsible person believes that the physical count is correct, the difference will be recorded.
- ✓ The group should make sure that all sections of the inventory forms that need to be filled before and during the inventory are properly completed, signed and submitted to the Pharmacy head.

Step 3. Analysis, Interpretation, and Reporting Steps (after physical count)

The pharmacy accountant in collaboration with pharmacy head/DSM head/dispensing unit coordinator must complete the section ‘to be filled after the inventory’. The inventory at the pharmacy store is valued based on the cost of medicines, whereas the inventory at the dispensary is valued based on retail prices of medicines.

Pharmaceutical coding

1. Internal Coding Systems for Products

Internal coding refers to the process of assigning codes to pharmaceutical products within the health facility so as to uniquely identify pharmaceuticals.

Drugs, laboratory reagents and medical supplies should be internally coded in health facilities.

The purpose of this coding is to ensure traceability of medicines and transactions at any point of service delivery without interrupting the continuous availability of medicines to patients.

Unless medical products are coded, it would be very difficult to trace products in situations of pilferage, loss and patient harm and ADR.

Coding is also extremely important to summarize daily sales of dispensed medicines manually or using cash registers and computers. There are several possible ways of coding for pharmaceuticals that can be utilized by health facilities. Health facilities can use any one of the coding systems depending on capacity and resources available.

Types of Internal Coding Systems

a. <u>Alpha Numeric Coding System</u>

This is a four letters and simple number coding system by using the first 4 letters of the drug name and following three digit numbers. The four letters refer to the first four letters of the generic name of a product. Example: Amox for amoxicillin or Para for paracetamol

In cases of product names with adjectives in the form of halogenations, methylations, acetylations, etc… (Example – Chloroquine, Chlorphenyramine, Chloramphenicol, Methyldopa, Methylpredinsolone, Acetazolamide, Acetylcystine), the first four letters of the name of the parent compound is taken. Example: *phen* for chlorphenyramine and *dopa* for methyldopa.

In cases of salts, and drug combinations where the name contains more than two or more separate words, the first two letters (for two combinations) or first two letters and one from each (for three combinations) or one letter (for four combinations).

Example: *masu* for magnesium sulfate, *amcl* for amoxycilline + clavulanic acid, *arlu* for artemether + lumefantrine, *oxhp* for oxytetracycline + hydrocortisone + polymyxin B and *mtah* for magnesium trisilicate + aluminium hydroxide).

Next to the first four letters, assignment of numbers is based on the strength of the product. Numbering starts from the smallest strength to the highest (e.g. 01 for 250mg and 02 for 500mg).

The number that comes immediately after the letter refers to the dosage form of the product and is it called the *base code*. The base code for tablets/capsules, suspensions/syrups, injections, drops, creams/ointments/pastes, suppositories/ pessaries and powders, etc… vary accordingly.

1	Dosage Form	Base Code Range
2	Capsules and tablets	Coding start at 01 and ends at 09
3	Oral suspensions/syrups	Coding start at 10 and ends at 19
4	Injectable	Coding start at 20 and ends at 29
5	Eye /ear drop/ suspension/ointments	Coding start at 30 and ends at 39
6	Skin cream/ ointments	Coding start at 40 and ends at 49
7	Suppositories	Coding start at 50 and ends at 59
8	Vaginal tablets/pessaries	Coding start at 60 and ends at 69
9	Other dosage forms	Coding start at 70 and ends at 79

For a drug having the same generic name, strength and dosage form but with different cost, the code may or may not vary. In cases where we use variable cost – variable coding, the last numerical digit of the code of the product varies by increasing the last digit.

The last numerical digits of the first code will start with number one for the first price, and increase sequentially as the cost of the same product differs. For example, if the code of Amoxicillin 250mg

capsule with a cost of 10 Birr is Amox011, then the code of Amoxicillin 250mg capsule with a cost of 20 Birr will be Amox012.

In cases where we use variable cost-fixed coding, the code remains the same irrespective of variations of the cost. In such situation, a product with a revised price cannot be shelved for dispensing prior to finishing the already existing one. In addition, when the product with the old price is completed, announcement of cost variation is mandatory before initiating of dispensing from the product with revised price. All dispensers using the sales ticket should immediately note the change in price.

Example:

SN	Description	Cost	Fixed Coding	Variable Coding
1	Amoxicillin Capsule 250mg	1 birr/capsule	Amox01	Amox011
		1.25 birr /capsule	Amox01	Amox012
2	Amoxicillin Capsule 500mg	1.50 birr/ capsule	Amox02	Amox021
		1.75 birr/ capsule	Amox02	Amox022
3	Amoxicillin Injection 250mg inj	4 birr/vial	Amox20	Amox201
		7 birr/vial	Amox20	Amox202
		8 birr/vial	Amox20	Amox203
		9 birr/ vial	Amox20	Amox204

6. Bin-Location Coding at Dispensaries

Bin location is a small compartment of a shelf in which part of a stock at the dispensary is shelved.

Bin location coding refers to the assignment of unique identifier/numbers to each location in shelves. The purpose of this coding is to facilitate the inventory management process by creating a systematic arrangement (pharmacological or alphabetical or dosage form, etc…) of stocks at the dispensary. In addition, coding bin location and subsequent assignment to respective bin owners enable to implement shared responsibilities among dispensers.

If shared responsibility is not implemented effectively, it might lead to locking of bin locations by owners and this may in turn severely compromise access to medicines (even lifesaving ones) prescribed to clients at the time when the bin owner is not available due to multiple reasons.

a. Numeric Bin Location Coding

For coding bin locations, a six-digit numeric characters can be applied (e.g. 100-001).

The first three digits represent the rows and the next three digits represent the columns. The first bin of the first row from the top takes a shelf number 100 and the first bin of the first column from the top takes a shelf number 001 and its code at the end becomes 100-001. Accordingly, all bins inside shelves will have unique bin location number.

100-001	**100-002**	**100-003**	**100-004**	**100-005**
200-001	200-002	200-003	200-004	200-005
300-001	300-002	300-003	300-004	300-005

b. Coordinate (X, Y) Bin Location Coding

In this type of coding, we use the simple (X, Y) coordinate system to label bin locations at the dispensary.

(1,1)	(1,2)	(1,3)	(1,4)	(1,5)
(2,1)	(2,2)	(2,3)	(2,4)	(2,5)
(3,1)	(3,2)	(3,3)	(3,4)	(3,5)
(4,1)	(4,2)	(4,3)	(4,4)	(4,5)

2. Responsibilities of Bin Owners (Dispensers)

- Receives medicines issued from the store
- Labels the codes, selling prices and/or retail prices on each package
- Shelves the medicines into the bin location
- Follows the expiry dates of drugs in each bins assigned to him/her
- Provides all the necessary information required to complete Model 20/1
- Follow the movement of stocks (fast moving, slow moving, dead stock, near expiry, etc…) and report to head of the dispensing unit.
- Control the inventory from theft, pilferage and other losses, take inventory when there is suspect, and perform random audit (whenever necessary) along with the pharmacy accountant, auditor or head of pharmacy unit
- Makes sure that the his/her bin location is adequately stocked and is accessible to other dispensers all the time
- During the quarter inventory, fill-in the inventory sheet and make it ready for physical inventory
- Report the average monthly consumption of drug in his/her bins to head of the dispensing unit.

7. Receiving of Medications at Health Facilities

Receiving of pharmaceuticals takes place using a receiving voucher Model 19/1.

Model 19/1 is a serially numbered official receiving voucher prepared in four copies and published by the regional bureau of finance and economic development and regional health bureau.

It is used to receive pharmaceuticals that come into the health facility through procurement, transfer, donation or other means.

The process of receiving products

The store manager receives the delivery invoice from the deliverer and crosschecks the physical count with the items and quantities stated in the delivery invoice. The store manager conducts physical inspection for any product defect or discrepancy. The store manager transcribes the list from the delivery invoice into the receiving voucher (Model 19/1). The store manager gives a unique internal code for each item, shelves and updates the bin card accordingly.

The store manager distributes the original (along with the delivery invoice) to finance (pharmacy accountant), first copy to the deliverer, second copy to the stock card clerk and the last copy remains with the pad. The stock card clerk updates the stock card. For those pharmaceuticals that are received without cost, the facility drug supply management officer or head pharmacist estimates the cost in consultation with the finance office and gets it approved by the head of the health facility.

Immediately after the accountant receives the original copy of Model 19/1, he/she sets both the selling and retail price in consultation with the head pharmacist. The accountant distributes both selling and retail price along with the product code to the store manager.

3. Requesting Medicines from Pharmacy Store

Model 20/1 is an official requesting form prepared in single copy and printed and distributed by the health facility. It is used to request pharmaceuticals from the pharmacy store by filling in and reporting all relevant information indicated in the internal facility reporting and requisition form (Model20/1).

The process of requesting Medicines

- ► The responsible person from dispensing outlets and service units completes part of Model20/1 (refer Model 20/1) and submit it to the store manager
- ► In situations where there are more than one bin owners, each bin owner should identify items to be requested and stocked in their respective bin locations.
- ► The store manager calculates consumption, the amount needed to arrive at maximum for the requisition period, fills in the quantity to be approved and submits it to the drug supply management officer or chief pharmacist of the facility for approval
- ► The store manager transcribes the list from the approved Model 20/1 into the issuing voucher (Model 22/1)

4. Issuing Medicines from Pharmacy Store

Model 22/1 is a serially numbered official issuing voucher prepared in four copies and published by the regional bureau of finance and economic development and regional health bureau. It is used to issue pharmaceuticals from the pharmacy store.

The process of issuing Medicines

- ► The store manager receives and transcribes the incoming approved requisitions and proceeds with the processing of issuing vouchers (enters all information including the internal code, cost and prices)
- ► The store manager signs on the voucher and delivers the requested items to the dispensing outlets and service units
- ► The responsible person from the requesting unit reconciles the dispatched items with those listed in the issue voucher and confirms receipt of product by signing on the issue voucher.
- ► The head pharmacist or his/her delegate approves by signing on the issuing voucher (as approver of receipt) for dispensing outlets

This voucher should be prepared in quadruplicate; the first copy (original) will be sent to the accounting unit of the pharmacy, the second copy to the receiver, the third copy to the stock card clerk and the fourth will remain with the pad. The approved request should be attached to the issuing voucher that remains in

the pad. The store manager updates the bin card accordingly from the copy which remains attached to pad. The stock card clerk updates the stock card from the third copy of the issue voucher.

5. Sales of Medicines

The sales of medicines refer to the transactions between the client/patient and the service provider at dispensing outlets and service units. This transaction involves sales of medicines on cash or credit or free including exempted health programs (e.g. TB, ART, Immunization, etc…).

a. **Sales Ticket Pad Register**

It is a register used for controlling the movement of sales ticket pads issued to and returned from dispensers. It identifies sales ticket pads by their serial numbers.

The pharmacy accountant should distribute sales ticket pads to all dispensing outlets and service units after recording all the details in the register. The pharmacy accountant requests and receives sales ticket pads from the hospital property administration store.

Every service provider at dispensing outlets and service units requests sales ticket pads from a pharmacy accountant. The accountant receives used sales ticket pads after checking and segregating it by used, lost, voided and/ or damaged pages and getting the signature of the returnee.

Note: Service providers are accountable for lost, damaged, voided sales ticket leaves and therefore, will have to confirm such incidences with their signature on the sales ticket pad register.

b. **Cash Sales Ticket**

Cash sales ticket is a receipt delivered to clients/patients in exchange of payment of cash. It is often a serially numbered triplicate copy consisting of 50 pages per pad, each bearing the name and address of the health facility. It serves both as a sales ticket and a legal receipt of the health facility for medicine sales.

Procedure for processing cash sales of medicines

- The patient delivers the prescription to the dispenser
- The dispenser checks the prices of medicines and informs the patient about the available options and get his/her consent prior to billing
- The dispenser completes the sales ticket, signs and delivers the first two copies (original and first copy) to the patient for payment. However, the delivery of the sales ticket to the cashier should be taken care of by the dispenser whenever possible.
- The dispenser retains the last copy of sales ticket with the pad for use by the pharmacy accountant.
- Procedure for processing cash sales of medicines
- The patient delivers the prescription to the dispenser
- The dispenser checks the prices of medicines and informs the patient about the available options and get his/her consent prior to billing
- The dispenser completes the sales ticket, signs and delivers the first two copies (original and first copy) to the patient for payment. However, the delivery of the sales ticket to the cashier should be taken care of by the dispenser whenever possible.
- The dispenser retains the last copy of sales ticket with the pad for use by the pharmacy accountant.
- The cashier ensures that the serial number of sales tickets, delivered for payment, is consecutive and inform to the respective dispenser otherwise.
- The cashier checks the price (unit/sum) and collects the right amount of money from the respective clients. In cases of price discrepancy, he/she shall inform to the respective dispenser for correction.
- Then, she/he signs the sales tickets, delivers the original to the client and retains the second copy.
- The cashier informs the client to please collect his/her drug at the dispensing counter.
- The dispenser retrieves the medicines from the shelves and delivers it to the counseling pharmacist along with the prescription.
- The counseling pharmacist verify the prescription with retrieved medicines and the sales ticket, prepare and fix the labels, and dispenses the medications to the patient with appropriate advice and counseling.

- ► The original bill is returned to the client with sympathy

Note: Billing two customers with one receipt is forbidden.

c. Credit Sales Ticket

This is a receipt delivered to clients/patients in exchange of presenting a prescription paper, identification card and prior notification of credit sales agreement from the sponsoring organization.

It is the same as the cash sales ticket except the name "Credit Sales Ticket". It serves both as a credit sales ticket and a legal receipt of the health facility for medicine credit sales.

d. Free Medicines Dispensing Register

This register is a recording tool to keep track of clients served by the pharmacy free of charge on the basis of evidence of confirmation of being beneficiaries of exempted programs.

8. Daily Summary of Cash/Credit Sales and Services

Daily summary is a single copy sheet that is used to summarize the daily sales and services given by dispensers and other health service providers. It is also used to monitor the daily financial flow and transactions of medicines and medical supplies within the health facility. The daily summary is prepared by the pharmacy accountant on a daily basis and documented properly.

Steps to be followed

- ► The accountant receives the second copy of cash sales ticket from the cashier
- ► Segregate the sales tickets based on its serial number and identify the tickets which are used properly, voided/lost, damaged and over or under priced by the dispenser
- ► Complete the daily summary sheet for cash sales properly
- ► In cases where there are voided, damaged or over and underpriced sales tickets, the accountant should get the signature of the dispenser in the corresponding raw for taking responsibility.

- ► Calculate the total compounding fee/other services fee, if any, and segregate from each sales ticket.
- ► Calculate the total over/under priced by all dispensers per day and take appropriate measure

In order to calculate the daily adjusted total sales (of both medicines & services):

- o Deduct the total daily overages from the total daily sales (of medicines and service charges) and
- o Add total daily shortages to the total daily sales (of medicines and services)

- ► Compare the bank deposit slip with total daily sales (of both medicines & services). If there is any discrepancy, the source of error is due to either over collection or under collection of cash by the cashier.

In order to calculate the daily total adjusted sales for medicines:

- o Deduct the total daily overages and compounding/services fee from the total daily sales (of medicines and services) and
- o Add total daily shortages to the total daily sales (of medicines and services)
- o The result is a daily adjusted total sale of medicines and this will be used by the internal and external auditors to calculate the total cost of sales of medicines for the day.

Notes:

- o The total number of drugs dispensed (by type) is approximately equal to the total number of counseling made to clients per day by all dispensers.
- o The total number of sales tickets is approximately equal to the total number of patients served.

9. Stock Turnover Ratio (STR)

Stock turnover ratio or inventory turnover ratio is a relationship between the cost of medicines sold during a particular period of time and the cost of average inventory during that particular period. It indicates the number of time the stock has been turned over during the period and evaluates the

efficiency with which the health facility is able to manage its stock of medicines. STR measures the velocity of conversion of stock into sales.

Usually a high stock turnover velocity indicates efficient management of inventory. Because, the more frequently stocks are sold/dispensed, the lesser amount of money is required to finance the inventory.

A low stock turnover ratio indicates an inefficient management of stock. A low STR implies over investment in medicines stock, stock accumulation, accumulation of obsolete and slow-moving medicines and low profit as compared to total investment.

It is calculated as follows

STR =The cost medicines dispensed or sold during the month

Average inventory at cost during the month

Average Inventory

Average inventory ➔ Beginning inventory + ending Inventory

2

Stock Status Analysis

EI = (BS + Stock received during the month)-Stock sold or dispensed during the month

based decision making on utilization of current stock and future procurements. This process enables the health facility to minimize wastages and ensure effective and efficient utilization of budget and continuous availability of essential medicines.

Steps to perform SSA

1. Identify medicines that are subjected to the stock status analysis (SSA). These medicines are identified after conducting ABC analysis and ABC/VEN reconciliation. Medicines that are candidates for SSA are:

    - Those that fall in A category (in the ABC analysis)
    - Those that are non essential in the VEN categorization and at the same time fall in the A category during ABC value analysis
    - Medicines with near expiry regardless of its category (in either ABC or VEN categorization)
    - If during a quarterly inventory, a product is found to have very high total cost as compared to other medicines in the inventory.

2. Calculate average monthly consumption of all medicines subjected to SSA. Average monthly consumption (AMC) is calculated as:

    AMC=consumption of a recent quarter/3-days out of stock in months

3. Calculate the months of stock for all medicines subjected to SSA. Month of stock is the number of months that can be covered by the stock at hand and stock on order provided that consumption pattern remain constant

    Months of stock=total stock at hand and on order/average monthly consumption

    N.B

    - In situations where the monthly consumption is increasing with time, use last month consumption instead of average monthly consumption as a denominator to calculate months of stock.
    - This calculation is valid only when the remaining shelf life of the product is greater than the months of stock.

4. Calculate the amount of stock that can be consumed before the product is expired. This is calculated by multiplying the average monthly consumption with the remaining shelf life in months.
5. Calculate the presence of over stock of a product. Over stock is calculated by subtracting the amount of stock that could be consumed until expiry from the sum total stock at hand and on order. When there is incidences of overstock, the facility should transfer it to other health facility or inform the concerned authorities for redistribution.
6. Calculate the additional stock needed to reach the maximum stock (i.e. for the 4 months). This is calculated as: Additional stock needed to reach to the maximum = AMC x (4 - Months of usable stock). If the result is negative, it indicates the presence of over 4 months stock and the facility can consider transfer to other health facilities.

6. Monthly Service Reporting

1. Number of Patient Served = #cash sales tickets + #credit sales tickets or #patients on credit sales register + #free patients
2. Average number of patients per dispenser = Total # patients served divided by number of dispensers
3. Number of Counseling Made in the Month per dispenser = #drugs (by type) dispensed to credit, cash and free clients by each dispenser Obtained from daily summary.
4. Average number of drugs per encounter or patient = #drugs (by type) dispensed to credit, cash and free clients / #patients Obtained from daily summary
5. Average price of Drugs Dispensed Per Patient = Total sales / (#cash sales ticket + #credit sales ticket or #patients on credit sales register)
6. Average price of a single drug=Total sales / total number of drugs by type
7. Affordability of drugs dispensed in the health facility = Average prices of drugs dispensed for a single patient of those who spend out-of-pocket divided by per capita income of smallest salary paid to a single government employees.

2.29 Legal frameworks enacted to implement APTS

Implementation of APTS requires legal framework due to the following basic reasons:

- To offer the appropriate due attention for medicine supply, distribution, medicine use, giving service, allocating appropriate number of professionals, creating good pharmacy service dispensaries as well as medicine information recording and utilization
- To correct social and economic impediment resulting from misuse and fraudulent, illegal medicine transfer and unfair pharmaceutical budget utilization
- To eradicate health problem as well as economic crisis that occur upon the people due to irrational use of medicines
- To use the government finance documents of pharmaceutical administration to have transparency and accountability of medicine supply process and service delivery, and to make auditing conducive, as well as build the financial capacity of health institutions
- To lay down a system for organization of the pharmaceutical departments, handling of information, human power deployment and utilization, leadership, and service delivery to satisfy customers' demand and utilize scarce resources allocated to the sector in a proper, efficient and effective manner
- To assure the provision of safe, effective, and quality assured medicines to the public by considering affordability and by giving good pharmacy services

Accordingly, the implementation of APTS requires a comprehensive legal framework as it affects pharmacy and finance workforce deployment, changes in financial documents, management of pharmaceutical finances, infrastructures, and others. It also makes possible the enforcement of the interventions and ensures accountability. Recognizing the benefits of APTS, Ministry of Health, all regional states and City Administrations of Ethiopia have enacted a legal framework for its implementation.

Note: Use the Federal regulations of APTS

Health Commodity Security

Commodity security (CS) is broadly defined as the ability to choose, obtain, and use health commodities when and where they are needed. It is a concept that has proven successful in identifying the gaps in access to groups of commodities and for developing strategic plans to address these gaps.

Countries can use CS framework to identify weaknesses or gaps at various levels and functions of the health system and develop strategies to address them.

Using this framework, countries can identify specific components of their health system to strengthen, such as the organization, service delivery capacity, infrastructure, staffing, and resources that support equitable access to and rational use of key health commodities. Once applied, countries can use the health commodity security (HCS) framework to monitor their progress toward attaining commodity security and to adapt or adopt the necessary changes for improvement.

WHO implemented variations of the concept in the following areas:

- ✓ Essential Medicines List (EML) and through the support of country specific lists and a Medicines Access Strategy.
- ✓ contraceptive security, where the right to choose among different family planning methods is introduced as part of ensuring that individual needs are met. A broader variation of CS, reproductive health commodity security (RHCS), includes contraceptives in its definition, as well as other essential commodities for reproductive health, such as medicines for maternal and prenatal use.
- ✓ Products to prevent and treat sexually transmitted infections (STI), and supplies for safe delivery.
- ✓ The CS concept has been further applied to HIV/AIDS commodities to improve routine availability and to help rationalize the selection and use of hundreds of essential health products for HIV prevention, treatment, and care.

Components of the Health Commodity Security Framework

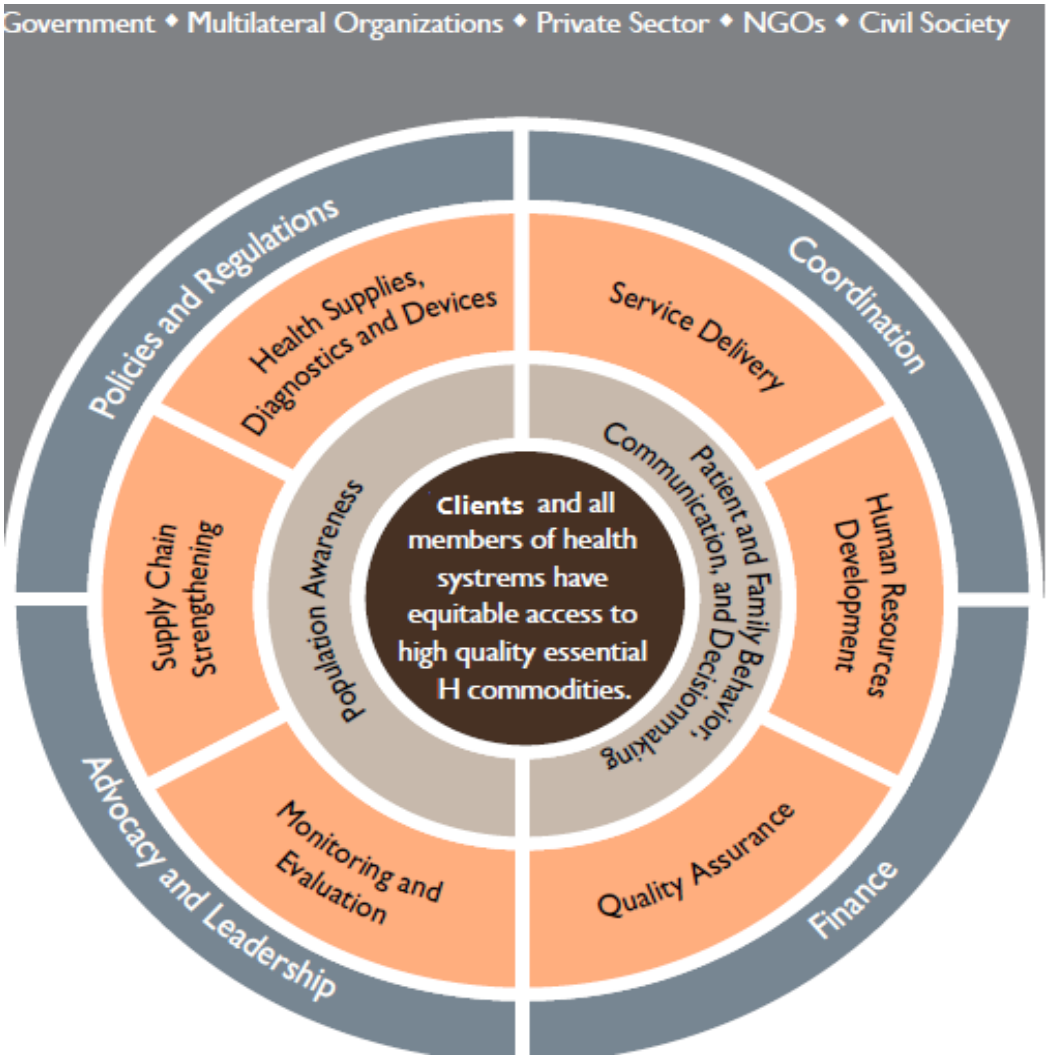

Government • Multilateral Organizations • Private Sector • NGOs • Civil Society
Policies and Regulations
Coordination
Advocacy and Leadership
Finance
Health Supplies, Diagnostics and Devices
Service Delivery
Supply Chain Strengthening
Human Resources Development
Monitoring and Evaluation
Quality Assurance
Population Awareness
Patient and Family Behavior, Communication, and Decisionmaking
Clients and all members of health systrems have equitable access to high quality essential H commodities.

Figure: Components of commodity security

The components of commodity security can be grouped at macro, meso (intermediate), and micro levels.

1. Macro (Policy and decision making) Level

The "macro" level of the HCS framework comprises the policy, economic, political, and organizational contexts.

At the macro level, the framework refers to the overarching architecture of the health system and its high-level stakeholders and decisionmakers. It includes elements such as:

- ► policies and regulations, coordination, financing, and advocacy and leadership.

Stakeholders at the macro level make decisions about the health system that inform the design, financing, and rights of beneficiaries of the system.

Policies and Regulations

Policies and regulations that directly or indirectly influence and support the public or private sector's role in securing health commodities are vital to shaping availability, quality, and affordability of key commodities. Policies and regulations for health commodities may be formulated using economic, demographic, and epidemiologic data. Supportive policies and regulations are elements of an enabling environment that signal government commitment to the availability of and access to high quality and affordable health commodities. Examples include the presence of the commodities in the country's Essential Medicines List (EML), importation and taxation considerations, and financial management policies.

Finance

Adequate and sustainable government funding for procurement of key commodities is critical. Government funding is necessary to support the public network of facilities and, where applicable, NGOs and private sector facilities. Funding is also necessary to perform other aspects of logistics management and the health programming, such as information, education, and communication (IEC) campaigns; training; and supervision. Sustainable financing policies must consider individuals' and families' out-of-pocket spending and minimization of financial barriers, especially for the poor.

Financing for key health commodities may come from a range of sources, including households,

third party payers (e.g., insurers, employers), governments, and donors.

The mix of funding sources may include government budget lines drawn from internally-generated revenues, donor grant funds, loan credits, or families' direct payments.

Funding support may also come from donors who provide direct financing of health programs or in-kind donations of health commodities and supplies.

Advocacy and Leadership

Advocates and leaders raise awareness for health supplies by actively engaging stakeholders to

address gaps in global and national plans, policies, and initiatives to increase the availability and use of medicines. Leaders and advocates can provide strategic input to advance the implementation of recommendations for increasing availability and use of the key health commodities.

A range of partners such as, civil society, academia, media, and other health partners can be effective advocates by participating in advocacy campaigns and activities. Advocacy efforts must

continuously inform policymakers, program managers, and development partners of the gaps and

effective solutions to address the gaps and support activities aimed at increasing availability and use of the key health commodities.

Coordination

Coordination is necessary across stakeholders, levels, and functions of the health system and should include both private and public sector.

Formal and informal coordination mechanisms, including councils and committees, with membership from a variety of stakeholders from different sectors should exist to facilitate information flow, efficient use of resources, and effective implementation of policies and regulations.

The different sectors include international and domestic donor organizations, government agencies, NGOs, social marketing and private providers, and technical agencies. Coordination mechanisms should be used to formalize processes, roles, responsibilities, ensure effectiveness of advocacy and monitoring efforts and prevent duplication of efforts.

The HCS framework requires a high degree of collaboration among stakeholders, including national governments, multilateral organizations, nongovernmental organizations (NGOs), the private sector, and civil society

2. Meso (Program) Level

At the "meso" level, the critical components of health programming are transformed from policies into programs. This level includes service delivery, human resources, health supplies, supply chain strengthening, quality assurance, and monitoring and evaluation.

Decisions made at the macro level result in programs created at the meso level. Organizational effectiveness and managerial decisions that influence service delivery, human resources, health supplies, supply chain, quality assurance, and monitoring and evaluation shape the programs.

Supply Chain Strengthening

Strong supply chains are necessary to increase access to key health commodities. Supply chain strengthening focuses on streamlining and standardizing processes at all levels and functional areas of the supply chain to address system problems and overcome challenges.

Supply chain strengthening activities can include system assessments, participatory design and implementation of in-country supply chains, development of national and sub national supply chain processes and procedures, capacity building in quantification and warehouse management, among others.

Service Delivery

The delivery of high-quality health services by healthcare providers must be organized around

the health needs of clients and their communities.

Healthcare providers must be guided by standard guidelines and protocols based on best practices and enabling policies for access and use of key health commodities.

Health Supplies, Diagnostics, and Devices

Accurate diagnosis of the health problems requires different diagnostics to detect abnormal hematocrit, blood pressure, and protein levels in the urine, among other things. Consumable health supplies

It is important to consider all the sectors; public, private, and commercial where health supplies, diagnostics, and devices are manufactured, distributed, sold, and purchased. Complementary

to understanding the need for and use of these services (and supplies), a health management information system (HMIS) is required to identify where these supplies are being used and where gaps exist.

Human Resources Development

Human resources are an essential component of high-performing health systems that meet the

needs of clients and service providers. Workers must be provided in sufficient numbers, they must be adequately trained, motivated, and competent in the skills required to fulfill the essential

roles required for the healthcare services.

Quality Assurance

The quality, safety, and efficacy of key health commodities are ensured through quality assurance measures, regulatory agencies, pharmaceutical producers, distributors, and other actors involved in medicines management. For medicines that require cold chain to maintain the stability and potency of products, quality assurance measures are especially critical to make sure the integrity of the product has been maintained throughout the supply chain. Drug registration and monitoring of good manufacturing practices are essential to ensure that only quality-assured products reach the marketplace.

Monitoring and Evaluation

Regular collection, analysis, and use of programmatic and population data for planning and decision making are crosscutting themes throughout the framework since monitoring and evaluation must occur at all levels of a health system, including at the macro and micro levels. Monitoring and evaluation provides evidence for determining programmatic adjustments.

National or subnational research studies, such as Demographic and Health Surveys (DHS) and behavioral studies should supplement these measures. An efficient monitoring and evaluation function supports managerial decision making by providing evidence to determine progress and by identifying challenges and opportunities for meeting strategic objectives.

3. Micro (Community) Level

The "micro" level of the HCS framework focuses on social contexts, family and community members, consumers and providers of goods and services, and the population. It focuses on behavior, communication, and decision-making processes.

The micro level focuses on the way individuals, such as patients and providers and families behave, communicate, and make day-to-day decisions. This level also includes population awareness.

Population Awareness

Increasing acceptability, demand, and use of key HCs is essential to improving outcomes. Awareness-raising campaigns and behavior change communication and interventions can influence the decisions health providers, managers, families, and patients make.

These types of interventions can inform health-seeking behaviors of individuals and families and help facilitate communication between patients and providers. Interfaces between these levels of the population are susceptible to weakening under various conditions, such as devolution, decentralization, or weak management systems.

Patient and Family Behavior, Communication and Decision making

Health-seeking behaviors, communication, and day-to-day decision-making processes of individuals and families, as well as provider biases and beliefs, are influenced by the various components of the health system such as awareness-raising interventions; these interventions can also help facilitate communication between patients and providers, as well as family and community members. They are also influenced by cultural considerations, biases, and religious

beliefs. The behavior and decisions made by the ultimate consumers of the goods and services.

1. Strategic pathway to health commodity security

Many countries face the challenge of meeting people's rising demand for health commodity security. Health commodity security exists when people are able to choose, obtain, and use the health supplies they want. It is not only a problem of increasing financing for supplies, but also of improving the systems

needed to make them available to people. Strategic pathway to health commodity security is an approach to help countries address these concerns and develop and implement strategies for health commodity security.

Strategic pathway to health commodity security is meant to initiate concerted action toward the goal of people being able to choose, obtain, and use the health supplies they want. It is not a roadmap, nor does a fixed process, but rather a guide that brings together the various factors that play a role in health commodity security.

Strategic pathway to health commodity security can bring together a wide range of stakeholders to:

- ✓ Establish and maintain multi-sectoral commitment to health commodity security by raising awareness and support for it as a public health objective;
- ✓ Conduct a multi-sectoral, joint diagnosis of a country's health commodity security status;
- ✓ Identify factors that limit or enhance the prospects for health commodity security;
- ✓ Process those findings to reach consensus on priorities for improving health commodity security;
- ✓ Develop a comprehensive, multi-partner strategy and action plan for health commodity security that is evidence-based, fundable and feasible; and
- ✓ Facilitate strategy implementation and guide ongoing monitoring and evaluation of results